EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	* MASTER FILE NO. 2:12-MD-02327 * MDL NO. 2327 * JOSEPH R GOODWIN * U.S. DISTRICT JUDGE	
THIS DOCUMENT RELATES TO ALL WAVE 5 AND SUBSEQUENT WAVE CASES AND PLAINTIFFS:	* General re Prolift+M, Prosima, TVT-O and TVT-Exact matter	
Monnica Reyes Case No. 2:12cv06141	*	
Shirley Terrebonne Case No. 2:12cv07779	*	
Jodi Valverde Case No. 2:12cv07999	*	

DEPOSITION OF MARSHALL SHOEMAKER, M.D.
PURSUANT TO NOTICE OF DEPOSITION
Taken on Behalf of Plaintiffs

DATE TAKEN: July 21, 2017
TIME: 8:53 a.m. - 3:13 p.m.
PLACE: Holiday Inn Express, 19751 South Greeno Road, Fairhope, Alabama

Examination of the witness taken before:

Debra Amos Isbell, CCR,RDR,CRR
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A P P E A R A N C E S

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I N D E X

DEPOSITION OF MARSHALL SHOEMAKER, M.D., 7/21/2017

EXAMINATION INDEX

EXHIBIT INDEX

I, Debra Amos Isbell, Commissioner and Court Reporter, certify that on this date, as provided by the Federal Rules of Civil Procedure, there came before me at the Holiday Inn Express, 19751 Greeno Road, Fairhope, Alabama, on July 21, 2017, commencing at 8:53 a.m., MARSHALL SHOEMAKER, M.D., witness in the above cause, for oral examination, whereupon the following proceedings were had:

(THIS DEPOSITION WAS TAKEN PURSUANT TO THE FEDERAL RULES OF CIVIL PROCEDURE. READING AND SIGNING BY THE WITNESS IS RESERVED.)

MARSHALL SHOEMAKER, M.D.
was sworn and testified as follows:
THE WITNESS: I do.

EXAMINATION

BY MR. RESTAINO:

Q. Good morning, Doctor. I've heard your name the way it's spelled as Shoemaker [shoo-mey-ker] or Shoemaker [shoo-maw-ker].

A. Shoemaker [shoo-mey-ker], just like it sounds.

Q. Just like Restaino.

A. Right.

Q. We met informally and now formally. I'm John Restaino. I'll be taking your deposition this morning a couple of times and tomorrow.

A. Perfect.

Q. So we'll get to know each other. Have you had your deposition taken before?

A. Yes.

Q. Approximately how many times?

A. Just one time.

MR. WALKER: Are you talking about in mesh or just in general?

MR. RESTAINO: Any time.

A. Yeah, one time. And it was in 2000.

Q. So seven years ago?

A. No. 2000, 17 years ago.

Q. 2000. Okay. 17 years ago. So I'll go over -- and I'm sure counsel has already discussed this with you. But the lovely lady to your left, my right, is going to take down everything we say.

A. Yes.

Q. If you and I met last night at a bar, we'd have a normal conversation; we'd step on each other's lines as we're talking. That's normal.

A. Right.

Q. It's going to make her job real hard. So if you will extend to me the courtesy of trying to listen for my question mark, I will do the same and try to listen for your period before I start my next question.

A. Perfect.

Q. We're entitled to your best testimony today, but nobody wants you guessing, nobody wants you estimating -- guessing. We might ask for an estimate.

A. Right.

Q. So therefore, I could ask you what's the estimated length of this table, and you'd come up with a number; what's the length of my dining room table, and it would be a pure guess. And nobody is asking you to do that.

This is not a memory test. If you need to review a document, you look at the document. Nor is this an endurance test. If the coffee exerts its physiological effect and you want to take a break, call time out whenever you want. I think between Jordan and I, we'll try to keep our eye on the clock and maybe every 10 minutes (sic) just get up, take a break, allow the court reporter to rest her hands a little bit if that works. However, once again, if prior to that time it kicks in and you just say, hey, I want to walk around for a moment, just go for it.

If you don't understand my question, please ask me to try to rephrase it. I cannot imagine that I would ask an unintelligible question. But if that rare event does occur, I will try to clean it up and make it understandable.

If, at the same time, you answer the

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question, the assumption is going to be that you understood the question at that time. Does that make sense?
A. Sure.
Q. Okay. There was a Notice of Deposition, and I've had the court reporter mark this as Exhibit 1. And I'm going to spend literally just a couple of minutes on this.
A. Okay.
(EXHIBIT 1 WAS MARKED FOR IDENTIFICATION.)
BY MR. RESTAINO:
Q. Have you seen this before?
A. I don't believe I've seen this.
Q. If you'll turn to the sixth page, at the bottom it says Schedule A. Do you see that?
A. Yes.
Q. It asks there for a number of items. And the first one is your CV. And I have a copy of your CV, which I'll go ahead and mark --
MR. WALKER: He brought one with him.
MR. RESTAINO: Okay.
MR. WALKER: I'm assuming they're the same.
MR. RESTAINO: Why don't we just compare

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them.
Q. Other than I can see some obvious redaction, are they the same?
A. Yes.
Q. Would you prefer the redacted one to be made part of the record? I mean it's redacting out your personal demographic information.
A. Okay. Sure.
MR. RESTAINO: So then we'll go ahead and mark his CV as number 2.
(EXHIBIT 2 WAS MARKED FOR IDENTIFICATION.)
BY MR. RESTAINO:
Q. You went to the University of Alabama?
A. Yes.
Q. For undergrad?
A. Yes.
Q. And what was your major?
A. Biology.
Q. And you graduated in '79?
A. '79.
Q. And then went over to Texas Tech School of Medicine?
A. Correct.

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Q. And then from there Parkland Hospital --
A. Correct.
Q. -- for your internship and residency?
A. Correct.
Q. Post residency did you do a fellowship?
A. No.
Q. At any time after residency in any type of formal educational setting, did you get advanced training in genetic oncology?
A. No.
Q. Maternofetal medicine?
A. No.
Q. Reproductive endocrinology and fertility?
A. No.
Q. Do you consider yourself an expert in gynecological surgery?
A. Yes.
Q. And when would you say you obtained this expertise?
A. Just because of the volume of procedures that I've done since I got out of residency. I have been fortunate to be very -- have a successful practice both in Texas for 10 years and then the last 20 years here in Fairhope.

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Q. Number 2 of schedule A of Exhibit 1 asks for documents in your possession not limited to correspondence, notes, videos, flash USB drives, photographs. Do any of these things exist?
MR. WALKER: Counsel, let me just kind of preempt some things here. I brought with me a thumb drive that has all of Dr. Shoemaker's General Reliance materials on it. And then we brought with us as well some hard copies of binders that he was sent that does not contain everything on here, but everything in the binders that we brought is going to be contained on this thumb drive.
MR. RESTAINO: Okay. That's perfect.
MR. WALKER: I don't know if you want to mark that or how you want to handle it.
MR. RESTAINO: Let's go off for a second.
(A DISCUSSION WAS HELD OFF THE RECORD.)
(EXHIBIT 3 WAS MARKED FOR IDENTIFICATION.)
MR. RESTAINO: And the materials that he brought, if you would identify them, we'll go ahead and mark that as an exhibit.
MR. WALKER: Yeah. So Dr. Shoemaker brought with him the Prolift Surgeon's Resource Monograph and

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the Prolift Guided Mesh PS prof ed materials to include instructional videos and instructional slides on implanting Prolift Guided Mesh PS.

He brought with him as well a number of binders that contain a portion of the materials on the flash drive that we've marked.

And I think there are a few pieces of literature. But I think frankly they might be more relevant to our SUI deposition tomorrow than Prolift.

MR. RESTAINO: And when we go off the record again and take a break, let's between the three of us discuss how we want to work the scheduling of this. We may be able to work this in such a way that tomorrow we leave some of the cleanup material and get you back to your family on Saturday a little earlier -- unless you want to stay here all day.

THE WITNESS: That is a magnificent idea.

MR. RESTAINO: So we'll see how that goes.

Okay. Next you mentioned an invoice. We'll go ahead and mark that then as 4.

(EXHIBIT 4 WAS MARKED FOR IDENTIFICATION.)

BY MR. RESTAINO:

Q. So I've marked as Exhibit 4 a document

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handed to me today. And it's an invoice, dates of service, March 24, 2017 to June 6, 2017, Ethicon litigation. And TVT report, POP report, reports total, 35 hours at $500 an hour. Case specific reports, three of them are listed for 21 hours at $500 an hour, for the total hours thus far, 56 hours at $500 an hour, $28,000.

Doctor, have you been paid yet?

A. Yes, I've been paid for that invoice.

Q. Okay. I'm assuming that there's prep time for today's deposition?

A. (Nodding head affirmatively.)

Q. I'm assuming you met with counsel prior?

A. Yes.

Q. And you will be charging for that?

A. Yes.

Q. Okay.

(A DISCUSSION WAS HELD OFF THE RECORD.)

BY MR. RESTAINO:

Q. During your medical school training, did you have formal classes on biomaterials?

A. No.

Q. And during residency did you -- strike that.

Sometimes some physicians in training will

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have a year or more where they're outside of the clinical didactic environment and they're in a laboratory doing research. Did you spend any time like that out of the didactic world, out of clinical medicine, doing research on biomaterials or any other thing?

A. No, we did not spend time doing that in our residency.

Q. So you did a straight residency, graduate medical school, do what in o'dark hundred was called an internship?

A. Correct.

Q. And then the remaining years were in OB-GYN residency; correct?

A. Correct.

Q. And if I understood from reading your report, when you first went into private practice, you did both obstetrics and gynecology?

A. Yes.

Q. Do you still do obstetrics and gynecology?

A. Yes.

Q. Now, when you were -- when you were a resident, were you involved in any type of research that led to publication in the peer-reviewed medical

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literature?

A. I was involved in studies by definition because we were doing big deliveries, lots of deliveries, and there were studies that were coming out of Parkland because it's a big research hospital. But I didn't do any specific papers with my name on it.

Q. Okay. In looking at your CV, I did not see a list of publications. And when I searched your name in PubMed, I didn't see any publications. Have you ever published in the peer-reviewed medical literature?

A. No.

Q. During your actual residency, did you receive training on the use of a mesh in the pelvis of women?

A. No. I finished my residency in 1987, so we didn't -- we weren't using mesh.

Q. As part of your residency, did you spend any time rotating through general surgery?

A. We did -- no, we did not. Didn't do hernia meshes either.

Q. That's where I was going. Now, when you first began to use vaginal or pelvic mesh, which

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device or implant was the first one you used?
A. When I was in Corpus, we -- probably '93, maybe '94, I'm not sure of the dates -- we did laparoscopic Burches. And we used mesh and staples. And it was a polypropylene mesh, but I'm not sure of the details. I don't remember the name of it, to be honest with you. But we did do mesh and staples to suspend the paravaginal tissue to Cooper's ligament.
Q. Okay. As you sit here today -- and this may be one of those estimate questions -- do you recall the weight and flexibility of that mesh you used versus the kit mesh that is available, for example, Gynemesh PS?
A. I do not remember.
Q. Just reading it in the different literature, let's see if we can agree early on. How do you personally -- how would you define in the context of vaginal mesh erosion versus exposure or intrusion?
A. I like to use the word "exposure" because that means that the mesh is visible. When you talk about extrusion, the data that I've read and what we've talked about earlier is that if you have some mesh that erodes -- mesh doesn't erode. But if you have a visceral injury that you find mesh in, usually

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because it was placed there wrongly, I would call that more of an -- that would be more of a -- what did we say?
Q. Extrusion, erosion?
A. Maybe erosion is a better word for that. But I use exposure for all my mesh -- everything that I do with mesh I use the word "exposure." It's easier for me to talk with the patients about it.
Q. Okay. I'll try to keep that in mind and use that as I go by. I may slip and say erosion on occasion.
Now, have you ever been invited to lecture at any national association/society meetings on the use of transvaginal mesh?
A. No. But I was involved in precepting doctors, and I was also involved in cadaver labs with Gynecare.
Q. Have you ever been asked to lecture nationally on Prolift+M?
A. Yes. But not at a national meeting. I would go to Austin and do a dinner talk for Prolift mesh. And then I usually would stay over and operate and help a surgeon do a procedure.
Q. And did those surgeons pay for your way to

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go there and do that? Or did you have to do that on your own or did Ethicon pay for that?
A. Ethicon paid for that.
Q. Did they pay your expenses?
A. Yes.
Q. Your time?
A. Yes.
Q. Okay. Have you at any -- for example, the national organization for OB-GYNs --
A. ACOG.
Q. ACOG. Have you been invited to lecture at ACOG on transvaginal mesh at any time?
A. No.
Q. Have you at any of those meetings held yourself out as an expert in the use of transvaginal mesh?
A. I haven't been to an ACOG national meeting in years because of time constraints.
Q. Do you have any formal training in epidemiology?
A. What do you mean by epidemiology?
Q. The incidence and prevalence of disease in the population.
A. I'm not trained to do that necessarily, no.

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Q. Just because of the studies we'll be looking at, which are epidemiological studies, I just want to go through some of them. Because I did notice in your report you talk about highest form of scientific evidence.
A. Correct.
Q. So talking about epidemiology, epidemiological hierarchy, in your report you mentioned the multicenter, randomized, blinded -- double blinded perhaps -- controlled, randomized controlled trial as being at the top.
A. Right. Well, actually meta-analysis at the top.
Q. My next question.
A. Right. Meta-analysis at the top.
Q. So we're now having a telepathic -- you would agree that a meta-analysis may be better than a randomized controlled trial?
A. It's the highest level of studies that we have that I rely on.
Q. In a pyramid of epidemiological evidence or strength below the randomized controlled trial we will find the cohort study, which is maybe prospective or retrospective. And there's a group with a disease,

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and they have a control group, and then they follow them. But they start with the disease. Are you familiar with that?

A. I'm familiar with cohort studies. But I also actually have the pyramid in my report. So we could go through that if you'd like to see how I base the meta-analysis and where I put cohort studies in that.

MR. WALKER: You're talking about a graphic representation?

THE WITNESS: Yes, correct.

BY MR. RESTAINO:

Q. In your expert report?

A. Yes.

Q. Why don't we go ahead and --

A. Find that?

Q. And mark your expert report.

MR. WALKER: And just to clarify, I think he may be referring to not something in the body of the report.

THE WITNESS: I have a graph that I read somewhere, and I put it in my report. It will take me a while to find it maybe.

MR. WALKER: Maybe we could find it on a

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break.

THE WITNESS: Okay. Yeah.

BY MR. RESTAINO:

Q. Do you have a visual or a recollection of this pyramid?

A. Yes. Except I get lost down the way.

Q. You're not the only one. There are people that get lost down there. But let's see if we can at least agree, and then we'll check this during one of the breaks. So at the top a well done meta-analysis would be placed there followed below by the randomized controlled trial?

A. Correct.

Q. Which is maybe multicenter and has randomization and is controlled; correct? Followed by the cohort study with the cohort of patients and a control group, could be prospective, could be retrospective. They start with the disease, and then they follow them and come out with causation.

Below that, getting weaker, is the case control study, which is typically retrospective where you'll look for an exposure, compare the odds of developing a disease with a control group; agreed?

A. That's correct, yeah.

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Q. Below that comes the hypothesis-generating case report or case series. Do you agree with that?

A. I believe that's what it is. I'll have to look for sure to make sure.

Q. Okay. And we can confirm that. Just so that we're on the same page going forward here, can you tell us what a case report is?

A. I think the best way to describe a case report is where you have an incidence of a problem or something good, and you review that and actually report on the case, exactly all the details and what happens associated with that.

Q. Okay. No control group?

A. No control group.

Q. No blinding?

A. I'd have to look. I'd have to see the specific report.

Q. Okay. And would you agree that a case series is two or more case reports?

A. Yes.

Q. Okay. Do you consider yourself an expert in the epidemiological design of any of those studies?

A. Well, I have to be able to interpret the studies and apply it to my specific practice and my

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specific surgeries that I do and how I perform my surgeries and what I elect to do. I use all of that together. So in some ways I'm an expert, but I don't design the studies.

Q. Okay. So no one has ever asked you to design a prospective case -- or a retrospective case control study looking at Prolift+M versus native tissue repair?

A. I have not been involved.

Q. Okay. Other than medical school and rotations during your residency, do you have any formal training in pathology?

A. Well, I can tell when I see gross pathology. And we did a pathology rotation, so I did look under the microscope at cells and abnormalities. But I have not done any formal training since my residency.

Q. And when would you have done that pathology rotation?

A. Oh, '85, 1985.

Q. Are you on staff at any hospitals today?

A. Yes.

Q. And at any time in those hospitals are you -- is Dr. Shoemaker called in to look at tissue and make a final pathology report?

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A. Not at this time.
Q. Have you ever been?
A. No.
Q. So you rely upon the residency, fellowship, perhaps trained pathologists?
A. Correct.
Q. Do you consider yourself an expert in the field of gynecological pathology?
A. Clinically, yes, I feel like I'm an expert in that. But as far as sitting under a microscope and looking at electron microscopy, probably not.
Q. In discussing material sciences and meshes, there's a brief discussion in your report about mesh shrinkage; correct?
A. Well, I'm not sure -- there is a report about mesh shrinkage, but it's more -- the data that I've reviewed looks like it's more the tissue contracts around the mesh. The mesh actually doesn't shrink.
Q. Okay. We're going to get into that a little bit and look at that. That may be one of those Shoemaker [shoo-mey-ker] / Shoemaker [shoo-maw-ker] moments --
A. Okay. No problem.

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Q. -- when we talk about what is shrinkage.
A. Gotcha.
Q. Have you ever conducted any animal research involving mesh?
A. I have been involved in a pig lab placing -- but that was before -- when we were doing laparoscopic Burches, that's how we learned that; worked in a pig lab. And I worked in a pig lab also learning laparoscopic procedures, supercervical hysterectomies, those kinds of thing.
Q. During your time in the pig lab, did you ever implant mesh anywhere into the pig to study it for any foreign body reaction, shrinkage, or any adverse event?
A. No, I did not.
Q. So you didn't -- you haven't done any pig or any other animal research using Prolift+M or any of the other meshes that we're going to discuss?
A. No.
Q. Okay. Has Ethicon ever approached you and asked you to engage in animal research with any of their meshes?
A. No, they haven't.
Q. And has Ethicon ever approached you and

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asked you to work on or redesign any of their meshes?
A. They have not.
Q. Have you ever removed from a woman a -- strike that.
Let's agree like on a true erosion and extrusion. My natural tendency would be to say vaginal mesh, but at times a more appropriate anatomical description might be pelvic mesh. Would you agree?
A. Yes.
Q. Are they so distinct that we should agree to say vaginal when it's vaginal or pelvic when it's pelvic, or is there a term that would encompass both that you're comfortable with?
A. Well, I would say vaginal mesh. I've never had to take a mesh out intraperitoneally. So it's vaginal mesh. Now, I have had the opportunity to take out vaginal mesh after an exposure.
Q. Can we agree that we'll use the term "vaginal mesh," but if something comes up and you say, wait, John, now there's a distinct difference and it would be more appropriate to use pelvic mesh -- but otherwise, we'll agree to use vaginal mesh for the next couple of days?

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A. I think that's fair.
Q. Okay. Have you ever removed a mesh product from a woman?
A. Yes.
Q. And was it a complete excision or partial or both?
A. Partial.
Q. Okay. Have you ever removed a Prolift M from a woman?
A. +M? Yes, I have.
Q. +M. And is that how you would describe it, as Prolift+M?
A. +M versus Prolift.
Q. And you have removed a partial excision?
A. Yes. Because of a small exposure.
Q. So you've never had to completely excise a full mesh?
A. I have not. In my experience, an exposure has been limited. And I would just dissect out the area that was exposed and not have any issues after that.
Q. Have you read in the literature of cases where there's frank contamination and infection of mesh and the mesh "enblanc" has to be excised?

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A. I have seen things in the literature regarding that, but I've never seen it. And I've never encountered it when I removed the mesh.
Q. Okay. When you have removed -- when you've conducted your partial excision of the mesh as you've described, did you send the mesh -- strike that.
Was that procedure performed in a hospital?
A. Yes.
Q. Was the tissue removed including the mesh then sent to pathology?
A. Sometimes it was, sometimes it wasn't.
Q. Okay. When you sent it to pathology, did you ever ask for electron microscopic evaluation of the mesh?
A. I did not. But I will say that I sent -- most of the time if I ever sent it away, it was because a patient had an attorney that wanted it. And really I would not send it to the pathologist. We had to put it in a sterile container, and then they took it and gave it to the patient.
Q. Okay. Do you have any formal training yourself in the use of electron microscopy?
A. I have not used the electron microscope.
Q. You're currently being paid $500 an hour to

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review records and draft reports?
A. Yes.
Q. And $700 an hour for your deposition?
A. Right.
Q. Why is there a difference between A and B?
A. Because depositions are a little more complicated.
MR. WALKER: That's fair.
BY MR. RESTAINO:
Q. And you indicated that in preparation for today's deposition, you met with counsel?
A. Yes.
Q. This would be the fine young, good-looking gentleman to your right?
A. Jordan Walker.
Q. Okay. And for approximately how long did you guys meet?
A. We met for three hours a week ago.
Q. Okay. Over dinner?
A. No. In my office.
Q. You should have made him buy you dinner.
A. He didn't even offer.
MR. WALKER: Oh, come on. You're killing me.

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BY MR. RESTAINO:
Q. At the Grand Resort.
A. Yeah, right.
Q. Next time. And I'm assuming you're charging Ethicon for the time that you met with him?
A. Yes.
Q. In your expert report, including your General Reliance and Supplemental Reliance Lists, did you review and/or actually read any of those medical articles and not charge for it?
A. No. I've charged.
Q. Yes. And the invoice that was listed has a number of hours for the reports. So TVT report, POP report, reports total, 35 hours; correct?
A. Correct.
Q. Now, does that time include your reading of medical articles, searching for medical articles, downloading the articles, all of that time also?
A. Yes. I also have another invoice that I have not turned in since June 6th.
Q. And could you estimate for us --
A. I'd say probably 30 hours. That includes meeting with Jordan and more review.
Q. Okay. In your General Reliance List -- and

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I'll mark that and show it to you in a moment -- there's a section called Production Materials. Do you remember that?
A. Yes. Can we look at it?
Q. Of course, yes.
MR. RESTAINO: Why don't we go ahead and mark this as 5.
(EXHIBIT 5 WAS MARKED FOR IDENTIFICATION.)
BY MR. RESTAINO:
Q. Do you see that?
A. Yes.
Q. Does that, as lawyers like to say, refresh your memory?
A. It refreshes my memory.
Q. Okay. Now, in those materials that are listed there in the General Reliance under "other materials," when you reviewed them, did you charge for your time?
A. Yes, I did.
Q. The articles that are cited in your expert report in your General Reliance, in your Supplemental Reliance Lists, did you find and download all of those articles off of PubMed yourself or did you have

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someone assist you in that?
A. I had someone assist me. I did do a PubMed search in the process of all this research. But I had a lot of these articles that I was able to draw from, you know, that were given to me, yes.
Q. Okay. When is the last time you actually conducted a PubMed search for your expert report or in preparation for your deposition?
A. About a week ago.
Q. When you're looking at these expert reports -- I'm sorry, strike that -- looking at these medical articles, how long does it take for you to read an article on gynecology, on mesh and epidemiological studies?
A. It depends. Sometimes it takes 20 minutes, sometimes it takes five minutes, sometimes it takes 35 minutes. It depends. It depends on what's involved. I really look at how many patients were involved. That makes a big difference when I start to look at an article. I like to look at -- I look at the conclusions, and then I'll look at the results and discussions. And I'll look at some tables. It depends on what the articles say, good or bad.
Q. So did you review all the articles that are

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in your expert report, your General Reliance, and your supplemental list, Supplemental Reliance List?
A. I reviewed -- put my eyes on every report that I saw. I don't know -- I don't remember seeing 100 percent of these -- I don't remember -- we'll have to look at these Ethicon, some of these Ethicon --
MR. WALKER: Are you talking about the company documents?
A. -- company documents. I'll have to look. If something comes up about that, I will look at it again.
BY MR. RESTAINO:
Q. Of course, yes. Now, the General Reliance List, it's approximately -- or maybe exactly -- I wrote down here 66 pages in length. And of those 66 pages, 46 of them, I will represent to you, are a listing of medical articles.
A. Right.
Q. Very close to 20 medical articles on a page. So there's about 900 medical articles.
A. Right.
Q. And you reviewed them all?
A. I at least looked at them, you know. Like I said, there's some that didn't take long to look at.

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Maybe a minute. But for the most part, if there was something and I really studied it, it took me a while to do it.
Q. But if you looked at something for one minute, if it's in your General Reliance List, I have the right to believe you're relying upon that article.
A. Correct, correct.
Q. Okay.
A. And if we need to, we'll look at it together.
Q. If you take a look at your General Reliance List, the very first one of the medical articles is an article by Abbott, et al., Evaluation and Management of Complications from Synthetic Mesh after Pelvic Reconstructive Surgery, A Multicenter Study. Do you see that?
A. Yes.
Q. But that's not in your -- it's not referenced in your expert report. How did you decide which ones were going to be referenced in your expert report and which ones were going to be relegated, if that's the right word, to your General Reliance List?
A. You know, it depended. Like this is from the Gray Journal. So a lot of times if I read

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something from the Gray Journal -- sometimes I may not put it in the report. But I tried to put almost everything I could in the report.
Q. Now, what do you mean by the Gray Journal?
A. That's the American Journal of OB-GYN. I get that publication every month. I don't have to look it up to get the study. Does that make sense?
Q. Yes. I have a copy of that study. It's been previously marked in a different deposition as Plaintiff's Exhibit 4130, but let's go ahead and mark it here as 6.
(EXHIBIT 6 WAS MARKED FOR IDENTIFICATION.)
BY MR. RESTAINO:
Q. Now, again, this is one that's not listed in your expert report. Did you read this article?
A. I have read this article, I believe, in the past. But I can't tell you exactly when and where.
Q. Okay. And I wouldn't ask you that. If you look at the abstract, you see study design.
A. Yes.
Q. And they write:
"We conducted a multicenter retrospective analysis of

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women who attended four U.S tertiary referral centers for evaluation of mesh-related complications after surgery for SUI and/or POP from January 2006 to December 2010."

Did I read that correctly?

A. Yes.

Q. And if you'd just take a moment to glance over the abstract. And of course, you have the right, if you need to, to look at the entire article. But my question is just going to be: As we discussed that pyramid of epidemiological hierarchy, this is a retrospective case series; wouldn't you agree?

A. Yes.

Q. There's no control group?

A. Right.

Q. There isn't any randomization. They just looked at the medical records from the patients and they obtained data from those medical records.

A. Right.

Q. And the conclusion is in the abstract:

"Most of the women who seek

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management of synthetic mesh complication after POP or SUI surgery have severe complications that require surgical intervention; a significant portion require greater than one surgical procedure. The pattern of complaints differs by index procedure."

Did I read that correctly?

A. Yes.

Q. But I didn't see anywhere in your expert report an opinion that's consistent with:

"Most of the women who seek management of synthetic mesh complication after POP or" -- tomorrow -- "SUI surgery have severe complications that require surgical intervention."

Is there a reason you didn't include that in your report?

A. Because the definition of "severe" is a bit

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of a problem even in this study. Some people would say that if you have to take somebody back to the operating room, that that is a severe complication. But if you go back to the operating room to take out a small piece of mesh, I don't consider that a severe complication. Not that I think that going back to the operating room is no big deal. It's very important. There's no such thing as a minor surgery. When it's surgery, it's a surgery. I'm not trying to advocate that at all. But I just think that taking someone back to surgery is not necessarily a severe complication. And that's where I differ as far as -- that's why I didn't mention it.

Q. Okay. Would you agree, however, there are complications that by almost any surgeon's definition would be severe?

A. There are situations that have -- there are some bad outcomes. No doubt about that.

Q. Now, as you sit here today -- and again, it's not a memory test -- do you recall how these authors publishing in the peer-reviewed medical literature, how they define "severe complication"?

A. I want to say the big number was return to the OR. And that's where I differ a little bit with

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it. I have to look and see where I'm looking here.

I'm sorry. Let me have the question again. I'm sorry.

Q. Sure. I'm just asking if you recall or you can find out from reviewing the article itself how these investigators defined "severe."

A. I'll have to read it. I'm sorry. I'm not sure what they -- oh, wait. Here it is right here. (Reading.) They had an expanded classification index surgery by type 347. It looks like a grade 4 -- is that right -- grade 4 is severe. It looks like they said -- you know, there were no deaths, no organ system failure, and the 4 was -- E was requires management by an operation with general anesthesia.

So they defined "severe" as any time you have to go back and have anesthesia.

Q. Okay. Now, to move on from this article, but just to put a period on it, your report does not state -- or I did not see anywhere in it where it states that:

"Most of the women who seek management of synthetic mesh complication after POP or SUI surgery have severe

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complications that require surgical intervention."
Correct?
MR. WALKER: Object to the form.
A. I feel like that just because they go back to surgery, that is not a severe complication.
BY MR. RESTAINO:
Q. Okay. Now, in your General Reliance List on page 46 --
A. Do you need this back, sir?
Q. No.
A. What was that?
Q. That's quite all right. Page 46 of your General Reliance List.
MR. WALKER: Counsel, the ones he's looking at are not numbered.
MR. RESTAINO: Jordan, the ones I gave you, I think I added numbers -- the pages on them.
MR. WALKER: No. (Indicating.)
MR. RESTAINO: No? Okay.
Q. Do you recall -- without wasting a whole lot of time, because this is just a minor point -- do you recall in your General Reliance List a listing for a 2003 (14-Day Rabbit Study) PSE 02-0579 Stamped Copy

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dated March 10, 2003, R&D?
A. No, I don't.
Q. Do you recall reviewing a 14-day Rabbit Study?
A. I bet I have, but I do not remember that off the top of my head. Unless you can tell me what it's referring to about the rabbit.
Q. I did not pull the study.
A. All right.
Q. I just wanted to know if you reviewed that study.
A. I can't recall.
Q. Have you at any time reviewed any animal, such as rabbit, studies in the use of mesh?
A. I have seen studies where they used mesh in rats and put MSDS studies -- I've reviewed those studies, some of those studies.
Q. Okay. Have you ever seen an animal study, including nonhuman primates, where they have actually taken the mesh and put it into the pelvis or the vagina of the animal?
A. I have not seen that study.
Q. Would you agree with me that typically in these animal studies they place the mesh on the dorsum

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or the back of the critter?
A. Correct.
Q. As an expert in gynecological surgery, would you also agree that before being an expert in gynecological surgery, you must become expert in the anatomy and physiology of the compartment of the body you're going to operate on?
A. I agree with that.
Q. Which is why you go to medical school first and learn anatomy and physiology and all of that. As an expert in obstetrics and gynecology, would you agree that the vagina is a very complex aspect of the human body?
A. Yes, I do.
Q. And unlike the dorsum of a four-legged critter -- let me strike that.
On the dorsum of a four-legged critter, the mesh, as you and I are looking at one another, the mesh is placed on the transverse plane; correct?
A. I'd have to look at it. I believe it is, yes.
Q. There are different planes inside the pelvis of a woman; would you agree?
A. Yes.

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Q. Transverse, frontal, sagittal or coronal, depending upon how you learned it, whether it's centimeter [sen-tuh-mee-ter] or centimeter [son-tuh-mee-ter]?
A. Right.
Q. Now, the pelvis of a woman is a dynamic environment with her sitting, standing, lying on her back, lying on her belly, lying on her side, walking, running, climbing stairs, having sex; agreed?
A. I would agree to that.
Q. None of that is happening on the back of a pig; right?
A. Correct.
Q. And in addition, the tissue in the vagina and the pelvis is different tissue with different hormonal responsibilities than the back of an animal; would you agree?
A. That's true. And that's why the mesh that we use is different than mesh that's used for hernia repairs or on the dorsum of the back.
Q. Now, one area in the production material section of the General Reliance kind of maybe in all honesty raised my eyebrow, and that would be -- I'll represent to you -- counsel, of course, has the right

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to say no, we want to stop and count for ourselves. But I'll represent to you that in the 32 production materials listed -- in the production materials listed, there are 32 videos. Do you recall seeing 32 videos?

A. I've probably seen many of them. I did not review videos in preparing this report.

Q. Okay. Because 10 of them are listed as anatomy videos.

A. Well, I'll tell you there are a lot of -- when we did the prof ed, we did see lots of videos. I mean we really did. They showed us videos. Every one was a little different. We all got to the same end point, but they would change it a little bit. Sometimes they would do a little 3-D different model, that kind of thing, just to review the anatomy for everyone because the anatomy is complex down there, down in the pelvis. So it's important that you know the anatomy well.

MR. WALKER: And Counsel, just to clarify, he did actually bring a few videos with him in terms of the prof ed materials.

MR. RESTAINO: Okay. Thanks, Jordan.

Q. Essentially my question is going to be: Did

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you spend time reviewing 10 videos of female anatomy and charge Ethicon?

A. No, I did not.

Q. Okay. And then there's also -- well, I'll represent to you it's on page 60. So six pages from the end or so there's a listing of some 70 depositions. Did you read all those depositions?

A. No. I read some of them, though. Well, I read many of them. I probably read 10 or 12 for sure depositions and looked through some. They're long.

Q. These depositions, they're long. And if you have some 35 hours there plus another 30, how did you review 900 medical articles, videos, depositions, production material? This looks like six months worth of work.

A. Right, that's right. Well, I will say that some of the depositions were the same doctors.

Q. Yes.

A. And so I didn't read -- you know, but I read several. I mean I read many of them.

MR. RESTAINO: Okay. I'm going to mark next, just so it's in the record and I don't forget -- I think we're up to 7 -- the Supplemental General Reliance List.

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(EXHIBIT 7 WAS MARKED FOR IDENTIFICATION.)

BY MR. RESTAINO:

Q. I'm going to hand this to you in one second. I just want to check something. Yes.

If you look at the first article in your supplemental list, it's the Abbott article that was number 1 on your General Reliance that we've marked as an exhibit to this deposition; correct?

A. Correct.

Q. So what is the purpose of your Supplemental General Reliance List?

A. Just to review some of the things that I went over to prepare this.

MR. WALKER: And I will state, Counsel, that he has brought with him a few of the articles that he reviewed and received prior to the issuing of his report that I think would be reflected on that list. I don't know if you want to mark them. But we did bring some of the new materials that are not captured by the report itself that he's looked at.

MR. RESTAINO: Okay.

THE WITNESS: This report was finished June 6th. So I have looked at some newer articles since

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June 6th.

BY MR. RESTAINO:

Q. So then the newer articles would go into the Supplemental Reliance List?

A. We can do whatever. I just brought them with me, so I haven't --

Q. No. I'm just trying to understand what the supplemental list is.

A. Yeah. That would be --

Q. Because when I picked it up and I looked at it, I went: The first article is the same. And I thought: I don't want to go through these two 66-page documents trying to figure out what's different.

So if I understand you correctly, there are a few new articles that came about after you wrote your expert report, and they're included in the Supplemental Reliance List?

A. They will be.

MR. WALKER: Yeah. I'll just state for the record they are, yes. We brought them here. Dr. Shoemaker did not actually prepare the reliance list itself.

MR. RESTAINO: Okay. Now we're going to mark as 8 your actual expert report.

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(EXHIBIT 8 WAS MARKED
FOR IDENTIFICATION.)
BY MR. RESTAINO:
Q. As we're going through these exhibits today and tomorrow, there are going to be some that we're going to go back to on occasion. There's also going to be some like that very first one, the early study of Abbott, we're not going back to that. So I'll try my best to say that one you might want to keep in front of you. The others, like your General Reliance List, we're not going back to that, we're not going back to the supplemental list. Obviously we're going to use your expert report.
A. Good. We have pages on that. We have page numbers. Okay. Gotcha.
Q. Yes. Good. Now, this is the expert report that's titled Expert Report of Marshall Shoemaker, M.D., Gynemesh PS, Prolift, Prolift+M, and Prosima; correct?
A. Correct.
Q. To be differentiated from the expert report that we'll discuss in some detail tomorrow; correct?
A. Correct.
Q. However, in reading them -- which has

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succumbed my life for the last week --
A. Lucky you.
Q. Consumed my life, I should say.
-- there's a lot of similarities between the two. And by that I mean your background, your training, and then a lot of background material on polypropylene that's not specific to Prolift+M versus the mesh we're talking about tomorrow; agreed?
A. Agreed.
Q. And so what I'm proposing to do is that we sort of just have today a general talk about those, and probably later on this afternoon we'll get to the studies that you've listed. And then tomorrow we'll limit it to the actual studies themselves regarding those other meshes and not go back and have another review -- I don't think we need, okay, tomorrow: Now, you went to medical school and now you did your internship. Do you agree?
MR. WALKER: Correct. That's why you've got the three hours for the first depo. You've got that. And two for all the others. Because you've got the one hour today to cover the general background information.
MR. RESTAINO: Let's go off the record for a

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moment.
(A RECESS WAS TAKEN FROM 9:48 A.M. 9:55 A.M.)
BY MR. RESTAINO:
Q. I think we left off with the expert report. Now, you start off the report by writing that:
"This report contains my opinions regarding the design, safety, and efficacy of the Gynecare Prolift Pelvic Floor Repair System, Gynecare PS Transvaginal Mesh, Prolift+M, and Prosima. It is my opinion that all these products were safe and effective and provided adequate warnings and instructions to doctors."
Did I read that correctly?
A. Correct.
Q. Now, is it your understanding that in or about 2001 the FDA reviewed the first surgical mesh indicated for repair of pelvic organ prolapse and found it substantially equivalent to surgical mesh

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indicated for hernia repair?
A. I'm not sure of the question. Say that again.
Q. Is it your understanding that the mesh that became available for pelvic organ prolapse was based upon the safety and efficacy of the mesh used in hernia repair?
A. Even though it was a different kind?
MR. WALKER: I just need to clarify. Are you talking about an Ethicon mesh or just in general?
MR. RESTAINO: That's a good question.
Q. Let's limit it to the Ethicon mesh that first became available. So when Gynemesh PS came out, when you first studied it, were you given phase 1, phase 2, phase 3 studies?
A. I may have -- you know, I have to think about that. I may have been given that information. But I know that it was different than the hernia mesh.
Q. Okay.
A. The idea about hernia mesh that they talked about is just the fact that you get in-growth, tissue in-growth and all that kind of thing. But it's always, as far as -- since I've been involved with Gynemesh, it was always involved with the difference

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between the vagina and abdominal wall.
Q. Do you have any understanding of the 510(k) approval process?
MR. WALKER: Object to form.
A. I have read those things and I know I looked through that, but I'm not familiar with the details of it.
BY MR. RESTAINO:
Q. Have you had any discussions with anyone about predicate devices, meaning a device that exists on the market and another device comes along that is substantially similar, so therefore it does not need to go through clinical testing?
A. I've heard of those things. And I think -- I want to say -- and I don't know, I may be -- "guessing" is not the right word. But I know that when the other products for mesh came on the market, the other companies, they always would -- when they would come to me, they would always come to me to get me to try to use it. It was always they were using Gynecare's data. They were always trying to compare themselves to Gynecare. So I know that some of theirs probably got -- some of the other companies' meshes got predicated by Gynecare.

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Q. And do you know what Gynecare was predicated upon?
A. I do not know that, if it was. I don't know if it was.
Q. Have you heard of -- well, we'll get to it in a moment. Can you estimate for us how many Ethicon mesh devices you've implanted?
A. If you look at different compartments -- you want stress incontinence as well as -- you want slings?
Q. Yes.
A. I've done 1,300 or so slings and about 700 anterior and posterior repairs. Probably -- you know, if you use -- I always counted -- if you do an anterior and posterior, that was two. So about 700 -- over 700 pelvic floor repairs and over 1,300 slings.
Q. So collectively over 2,000 --
A. Correct.
Q. -- procedures involving the mesh?
A. Correct.
Q. The Ethicon mesh?
A. Ethicon mesh. 99 percent Ethicon mesh.
Q. Now, of any of the patients in whom you've put in any of the Ethicon meshes or any mesh, for that

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matter, did any of them postoperatively encounter excessive bleeding?
A. I have had in my experience bleeding after surgery.
Q. It can occur with mesh?
A. It can occur with surgery.
Q. Yes. When you had bleeding postoperatively associated with mesh, did you report that as an adverse event to the FDA?
A. I did not.
Q. Have you ever encountered organ damage during implantation of mesh?
A. I have not encountered organ damage.
Q. How about nerve damage?
A. Not prolonged nerve damage. Let me rephrase that. I've had pain issues, but they resolved. So nothing permanent in my experience.
Q. And when you've had the pain issues -- and so the record is clear, the patient had the pain issues; correct?
A. Correct; the patient had the pain issues.
Q. When you had the pain issues, did you make a diagnosis of what was the etiology of the pain issue?
A. Yes.

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Q. And did you report that as an adverse event to the FDA?
A. No. Because it resolved.
Q. Have you had patients in whom you've placed mesh who have developed post-op urinary frequency?
A. Yes.
Q. Did you report that to the FDA as an adverse event?
A. No, I did not.
Q. And can you define for us your definition of the word "dysuria"?
A. Pain with urination.
Q. And have any of your patients ever encountered that postoperatively following mesh implantation?
A. Not that persisted.
Q. It was short term?
A. Short term because of the cath.
Q. And how about incontinence?
A. Occasionally we had failures.
Q. Okay. Did you report them to the FDA?
A. No, I did not.
Q. Postoperatively any patients encounter urinary retention?

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A. Yes.
Q. And did you report that?
A. No, I did not.
Q. Postoperative urgency to urinate?
A. Occasionally there's been some situations.
Q. Did you report that to the FDA?
A. No, I did not.
Q. As with every surgery, patients in whom you've placed mesh would experience acute post-operative pain at some level; would you agree?
A. I agree.
Q. I can't think of any surgery that doesn't involve an ow?
A. Correct.
Q. Ow as in ouch. However, there's also an entity known as chronic pain; would you agree?
A. Yes, there are situations of chronic pain.
Q. How do you define or differentiate acute pain from chronic pain in a patient?
A. That's a difficult question to answer. You know, it's usually a period of time. So if someone has pain for one to two weeks, that's acute pain; after three to four weeks, probably chronic, could be chronic pain.

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Q. Have you ever had any women receiving mesh who you've diagnosed or at least thought to yourself she's having chronic pain?
A. I have had situations where I've had to remove mesh in a situation because it was placed wrong by myself. And we needed to get her pain controlled, and we did.
Q. Okay. Did you report that as an adverse event to the FDA?
MR. WALKER: Object to the form.
A. No.
BY MR. RESTAINO:
Q. With each surgery -- I can't think of one that doesn't involve it -- but the body goes through healing which involves the deposition of fibrotic tissue, and lay people may call that scarring; correct?
A. Correct.
Q. Can scarring occur within the vagina and/or pelvis of a woman following mesh implantation?
A. You know, it's interesting you say scarring, what the definition of scarring is. One thing about the wide mesh pores, you don't get -- you get incorporation of the mesh and not encapsulation of the

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mesh. So it's a different type of scar. So it doesn't have the significance, in my opinion, that a scarring would in another situation or in another -- abdominal wall mesh or something like that.
Q. Even using native tissue, there is scarring from surgery.
A. You can get scarring any time anything heals.
Q. Scarring can occasionally incorporate local nerves resulting in a localized nerve entrapment; would you agree?
A. It can, yes.
Q. Have you ever experienced that? Or has a patient of yours receiving mesh ever experienced that?
A. I have not had a nerve entrapment problem with any of my meshes.
Q. Can you define for us your definition of "dyspareunia"?
A. Dyspareunia is when you have painful intercourse. The reasons are multifaceted.
Q. And there's a term that I see bantered about in the literature now called "hispareunia." Are you familiar with that?
A. No.

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Q. H-I-S-P-A-R-E-U-N-I-A.
A. No.
Q. I've seen it used in some articles where they refer to the fact that dyspareunia is the pain that the woman is experiencing during sexual intercourse whereas his, H-I-S, is the pain that he's experiencing typically from irritation of exposed mesh. Have any of your patients come back to you and said not only is it hurting me but it's hurting my husband?
A. Usually when that occurs, it hurts the husband and the patient usually does not feel it. So the pain of dyspareunia isn't necessarily related to his pain as well. I've had many times when -- if the husband feels, palpates the mesh and it's uncomfortable on his penis during intercourse, that the wife doesn't know it. But he complains.
Q. As an adverse event, have you reported that to the FDA?
MR. WALKER: Object to the form.
A. No, no. I just fixed it, repaired it.
BY MR. RESTAINO:
Q. Have you had any women into whom you've placed mesh develop fistulas?

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A. I have not had a patient with a fistula.
Q. And how about recurrent prolapse?
A. I have had failures.
Q. When you have a failure, is that an adverse event that you report to the FDA?
A. No. Because it was usually an occult failure where we fixed one compartment and the pressure on the other compartment caused a failure in another compartment.
Q. And have you ever made a diagnosis of a woman with a mesh of a prolonged foreign body response?
A. I have not had a problem with foreign body response, prolonged foreign body response.
Q. In reviewing the medical literature, I noticed several authors stating that the complication rate related to vaginally placed mesh is not fully known because of incomplete knowledge of the total number of adverse events and the total number of vaginal mesh delivery systems that have been implanted. Would you agree with that?
A. That's a hard question to answer. Because, like I said, I've never reported to the FDA if I had a problem with the mesh. But these problems we were

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able to repair and fix without difficulty. I also can't speak to patients who didn't come back to see me. So it's easy for me to say my patients never had problems. But I don't know that necessarily. I do live in a small town, and patients do come back and see me. And I see them frequently and regularly. So I can't necessarily answer that. But they may be underreported. Some of the data says they're underreported. There's some data that says that the complications may be underreported, but I don't have any firsthand knowledge of that.
Q. Okay. On your expert report at page 2 you talk about where you joined the group of Parkland residents in private practice in Corpus Christi, Texas?
A. Correct.
Q. And that's when you discussed or mentioned your laparoscopic Burch procedures with mesh?
A. Correct.
Q. And for what conditions were you utilizing laparoscopic Burch procedures?
A. Stress urinary incontinence.
Q. And what is the benefit of laparoscopic procedure over an open procedure?

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A. Just less operative time and less pain postoperatively and we get them back to work more quickly.
Q. Would you agree that regardless of the anatomic location, when a patient has surgery with resultant healing, that area of tissue is never quite the same as Mother Nature designed it. So there's scarring. So whether, for example, someone is having a repeat carpal tunnel procedure, the fascial planes are obliterated to some degree and the area is just not normal.
MR. WALKER: Object to the form.
A. I'm not sure "normal" is the right word. It has changed. Definitely surgery changes the tissue, but it doesn't necessarily make it abnormal.
BY MR. RESTAINO:
Q. Okay. I understand what you're saying and respect you saying that. You've done abdominal procedures before?
A. Yes.
Q. Would you agree there that when going through the abdomen that has previously been operated on, there is to some degree the obliteration of the fascial planes through healing?

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A. It may be more difficult to identify fascial planes when you do a repeat abdominal procedure.
Q. Is it your experience in pelvic reconstruction surgery that repeat procedures have a higher failure rate than the initial procedure for the same condition?
A. It depends on who did the first procedure.
Q. Have you ever had patients where you've had a failure and you've gone back in to correct the failure from whatever cause?
A. Yes. And I have not had one that I had to go a third time.
Q. Okay. In this context of what we're saying, though -- and you can look at it. It's on page 6 of your report. You write:
"The healing and scarring caused by native tissue repair does not replace or add tensile strength; therefore, it does not restore and maintain normal function."
Can you explain to us what you mean when you write that?

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A. Yes. That's great. That's a good question. What happens is -- I'll give you an example of posterior repair. We have a defect in the posterior -- in the pelvic fascia and we try to put it together. In the old days before we had mesh augmentation, we would try to put it together. We'd find the defect -- put a finger in the rectum, find the defect, and then use Ethibond permanent sutures to reapproximate that. And we'd have great results for a while. And then that old tissue that's already torn would give away again. So it didn't increase the tensile strength. So that's why we'd have these -- that's why the failures. And these failures were real, even though we thought we did good repairs. And the failure rate was real.

And that's why, like I said, when I moved to a small town and started doing repairs when there was no one around doing them -- so I was doing them. And we were doing these repairs, and we had failures. That's when I got involved and needed something for augmentation. So that's how I got involved in the augmented repairs.

Q. I think that's a perfect segue to my next question, which is on page 3 of your report, I think

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it's the first sentence, you wrote: "After that" -- do you see where I am?

A. Yeah. "I became interested in the vaginal approach to pelvic prolapse."

Q. Yes.

A. The repair; right.

Q. Yes. And for the record, it states:

"After that, I became interested in the vaginal approach to pelvic prolapse and realized the significance for augmenting the repair because of the large failure rates from native tissue repair."

Did I read that correctly?

A. Yes.

Q. And that's what you were just discussing?

A. Correct.

Q. Now, how do you define "the large failure rate from native tissue repair" of POP?

A. I would say most of the data that I've seen is 25 to 40 percent. And I feel like my failure rate was not 25 to 40 percent, but it was still higher than

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I wanted. And that's when -- that dropped dramatically when I started augmenting my repairs.

Q. Now, I've struggled, not being by any means an expert in your world of gynecological surgery, of finding a good analogy, and I failed. The only one that I can recall is through orthopedics or podiatric surgery where we put the X-ray up on the X-ray box and look at it and go, ooh, that doesn't look good. And you ask the patient, and they say: No, I feel fine. In that particular case we were taught you operate on people, not X-rays.

Is there a similar situation in gynecological surgery; for example, if you have an anatomical prolapse but the patient says no, I don't feel it, I feel great?

A. This is my word to my patients, and I've been saying this for 30 years. It will never be a problem to me. When it bothers you, it bothers me, and we'll talk about it. So that's how I approach it.

Q. Okay. That was all context for when you discuss the large failure rate, how are you defining failure rate: objective anatomical prolapse, subjectivity saying this is bothering me, or repeat operation?

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A. It was absolutely -- in my situation with native tissue, if they came back and complained that the bulge was back, that was a failure. And that's when I augmented.

Q. But if they came to you and the bulge was back and they just looked at you and said I didn't know that --

A. Everything is fine. And I also won't bring it up.

Q. Now, on page 7, paragraph F, you write that: "In a 2016 Cochrane review" -- do you see where I am?

A. Yes.

Q. -- "Dr. Christopher Maher and colleagues, the authors found that, when comparing native tissue repairs to repairs utilizing mesh, the patients receiving mesh were less likely to be aware of prolapse at one to three years after the surgery."

Did I read that correctly?

A. You did.

Q. So this is one of the studies that I spent

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some time reading. This Cochrane review -- and I don't have the citation in the expert report from you right there. But I believe this is the 2013, not the 2016.

A. Yes -- no, this is 2016 is what I have here.

MR. WALKER: Hang on. Are you referring to the one you're about to hand him?

MR. RESTAINO: Yes.

MR. WALKER: It's 2013?

MR. RESTAINO: Yes.

THE WITNESS: Okay. I'm sorry. What I have is 2016.

BY MR. RESTAINO:

Q. You've referred to 2013 also; correct?

A. Yes.

Q. I think I read from 2013.

A. Okay.

Q. As I'm sitting here, if my memory serves me correctly, it's 341 pages. I didn't print out the entire 341 pages.

A. I probably did.

Q. You didn't have as far to travel as I did.

A. Exactly; that's right.

Q. I'm going ahead and mark -- what I've done

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for the record to make it clear is I made a copy of the front page, I skipped the many, many pages of the table of contents, and then went to the abstract section. And I've got a copy of this for you, which I'll give it to you in a moment.

A. We're still doing '13? I have '16, so I don't need that right now.

Q. Okay. Yeah, we'll get to that later. So we'll go ahead and mark, in essence, the cover page and the abstract from the 2013 Cochrane review.

A. Okay.

MR. RESTAINO: And this is going to be Number 9.

(EXHIBIT 9 WAS MARKED FOR IDENTIFICATION.)

BY MR. RESTAINO:

Q. Now, on the second page under abstract -- it's actually the first page but after the second page of the cover page -- do you see main results bolded on the lower left?

A. Main results, yes.

Q. And they write:

"56 randomized controlled trials were identified

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evaluating 5,954 women. For upper vaginal prolapse (uterine or vault), abdominal sacral colpopexy, C-O-L-P-O-P-E-X-Y, was associated with a lower rate of recurrent vault prolapse on examination and painful intercourse than with vaginal sacrospinous colpopexy. These benefits must be balanced against a longer operating time, longer time to return to activities of daily living, and increased cost of the abdominal approach. In single studies the sacral colpopexy had a higher success rate on examination and lower reoperation rate than high vaginal uterosacral suspension and transvaginal polypropylene mesh."

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Did I read that correctly?

A. Yes.

Q. So in fact, according to this Cochrane report that you're relying upon, the sacral colpopexy has a higher success rate on examination than transvaginal polypropylene mesh?

A. It is not -- well, in my hands it's not statistically significant. I don't do sacral colpopexies. I did abdominal sacral colpopexies before I moved here, but I don't do sacral colpopexies. So if somebody had a large vault prolapse and I couldn't repair it with a mesh augmentation, then I would refer those for a sacral colpopexy.

Q. Okay. But for the record, your personal experience is anecdotal; would you agree?

A. Well, it's in my hands; correct.

Q. And this is the Cochrane review, which is a meta-analysis of the randomized controlled trials?

A. There should be here the difference -- the percentage is better. I mean the difference in the success rate should be in here. It's not as much as we think.

Q. Well, okay. While it may be -- and we can

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pull out the entire study during a break and you can look at it -- the author is right as for the main results, that the sacral colpopexy had a higher success rate on examination and lower reoperation rate than the transvaginal polypropylene mesh; correct?
A. Okay.
Q. And this is, as we discussed earlier, the highest form of epidemiological evidence?
A. Correct.
Q. Agreed?
A. Yes.
Q. Now, that's not in your expert property, though, is it?
A. Well, everything I -- the gold standard was abdominal sacral colpopexy, and the Prolift data was in line with the sacral colpopexy but much less invasive of a procedure. And that's why.
Q. Okay. Then going back to what you wrote, again for the record, you wrote:
"In a 2016 Cochrane review,
"Dr. Christopher Maher and colleagues, the authors found that, when comparing native tissue repairs to repairs

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utilizing mesh, the patients receiving mesh were less likely to be aware of prolapse at one to three years after the surgery."
Correct?
A. Correct.
Q. And then the -- give me one moment. I just lost myself.
MR. RESTAINO: I'm sorry. Go off the record for just a moment.
(A RECESS WAS TAKEN FROM 10:21 A.M. TO 10:27 A.M.)
BY MR. RESTAINO:
Q. Returning to the Cochrane abstract from 2013, if you see six lines down from the top of the first paragraph, off to the left it starts with:
"Awareness of prolapse was also higher after the anterior repair as compared to polypropylene mesh repair (28 percent versus 18 percent ..."
And then they go through the relative risk

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of 1.57, 95 percent confidence interval 1.18 to 2.07. And you have written that in your expert report; correct?
A. Yeah. But everything I'm referring to in what we're reading now is from '16. And '16 doesn't have that. Do you see what I mean? I'm referring to the 2016 Cochrane review, and it doesn't have that. It's different.
Q. Okay.
A. You know, rates for repeat surgery for prolapse were lower with the mesh group, you know, there was evidence of -- you know, it talks about native recurrent prolapse on exam was less likely with the mesh group. This suggests 38 percent of women have recurrent prolapse after native tissue repair, between 11 and 20 for mesh. You know, that's what I'm saying. That's what I've referred to in this situation when I compared them.
Q. That being said, you've referenced the 2013 review; correct?
A. I'm trying to -- I may have, but I don't see that.
Q. Okay. Then let's move on.
A. I may have '13 in here. That is '13, isn't

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it? (Indicating.)
MR. WALKER: No. I think that's 2011.
THE WITNESS: That's '11.
MR. WALKER: There are several. Don't worry about it.
BY MR. RESTAINO:
Q. Okay. Give me a second here. Where I think my confusion came from is in your General Reliance List under medical literature -- it's actually on page 26 which starts with Luo, L-U-O, at the top -- you list Maher, Surgical Management of Pelvic Organ Prolapse in Women, Cochrane Review 2013, as one of the articles you're relying upon.
A. What date?
Q. It's the 26th page. It's not your expert report. It's in the general.
MR. WALKER: Fortunately we have these things alphabetized here.
MR. RESTAINO: I'm not sure why what I printed out doesn't have the page numbers. Is it up in the upper left maybe underneath the clamp.
MR. WALKER: You know what, you are correct, yeah. It was hidden.
MR. RESTAINO: Okay. Good. Because I added

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them when I saw the problem.
Q. So looking here on page 26, you see 10 down is Maher, Surgical Management of Pelvic Organ Prolapse, Cochrane Review 2013.
A. Right. So I have reviewed it. But when we're talking about this information, I was referring to '16. Does that make sense?
Q. Okay. But looking at the abstract for the 2013, when you state that -- in your report on page 7 in paragraph G you wrote:
"Native tissue repairs present the same risks as do repairs augmented with polypropylene mesh."
Do you see that?
A. Exactly, yes.
Q. But then looking at the Cochrane 2013 -- and we're going to have to be careful to delineate that -- what they actually say is that -- it's in, again, the first paragraph at the top, the fourth line from the bottom. It says:
"Blood loss (MD 64 millimeters, 95 percent confidence interval 48 to

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81), operating time (MD 19 minutes, 95 percent confidence interval 16 to 21), recurrences in apical or posterior compartment (relative risk 1.9, 95 percent confidence interval 1.0 to 3.4) and de novo stress urinary incontinence (relative risk 18, 95 percent confidence interval 1.0 to 3.10) were significantly higher with transobturator meshes than for native tissue anterior repair."
And then:
"Mesh erosions were reported in 11.4 percent (64 out of 563) with surgical interventions being performed in 6.8 percent ...)"
So this Cochrane review that is in your General Reliance List actually disagrees with your statement when you write that native tissue repair

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presents the same risks as do repairs augmented with polypropylene mesh; would you agree?
MR. WALKER: Object to form.
A. Well, if you look at this specifically, it may disagree. But what my point in this sentence was -- and I don't have it referenced -- was that the risk of vaginal surgery is the same whether you put mesh in or not except with the exception of mesh exposure.
BY MR. RESTAINO:
Q. Okay. But in many of the studies I've seen, there's increased risk of blood loss associated with mesh. Do you disagree with that?
A. There are probably some studies that say that.
Q. Okay. Now, again, returning to the Cochrane 2013, if you take a look at the very next paragraph, they state:
"Data from three trials compared native tissue repairs with a variety of total, anterior, or posterior polypropylene kit meshes for vaginal prolapse in multiple

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compartments. While no difference in awareness of prolapse was able to be identified between the groups (relative risk 1.3, 95 percent confidence interval 0.6 to 1.7), the recurrence rate on examination was higher in the native tissue repair group compared to the transvaginal polypropylene mesh group (relative risk 2.0, 95 percent confidence interval 1.3 to 3.1). The mesh erosion rate was 35 out of 194 (18 percent) and 18 out of 194 (9 percent) underwent surgical correction for mesh erosion. The reoperation rate after transvaginal polypropylene mesh repair of 22 out of 194 (11 percent) was higher than after the native tissue

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repair ..."
Did I read that correctly?
A. Correct.
Q. So the Cochrane review actually found no difference in awareness of prolapse between the groups undergoing native tissue repair versus a variety of total anterior/posterior polypropylene mesh compartments -- mesh in multiple compartments; correct?
A. Well, what they found was the reoperation for mesh was high, obviously, in the mesh group because there was no mesh in the native tissue group. This data does support that.
Q. Now, again, on page 7 of your expert report, you write that: "Mesh exposure, erosion, or extrusion" -- do you see where I am?
A. Let's see here. Where?
MR. WALKER: (Indicating.)
A. Okay. "Mesh exposure." Gotcha.
BY MR. RESTAINO:
Q. -- "erosion, or extrusion does not occur with native tissue repairs because mesh is not used, but suture exposure,

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erosion, or extrusion can occur with native tissue repairs."
Reference number 15.
A. Correct.
Q. "For instance, in the optimal trial, Barber and colleagues found that suture exposure occurred in connection with 15.4 percent of uterosacral ligament suspensions and 17.2 percent of sacrospinous ligament fixation 6 to 24 months after surgery."
Reference 16.
A. Correct.
Q. Okay. Give me a second. I want to pull up --
A. You want to get Barber?
Q. Yeah. Do you have Barber?
A. Uh-huh (positive response).
Q. If you can open up the study and take a look at it. Because, quite honestly, when I read it and searched it, I didn't find those figures at all. And

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in fact, I did a word search for 15.4 percent and 17.2 percent, and it didn't come up.
A. Here's a table. Let's see here. What are we looking for again? The number?
Q. Well, those two numbers. I wanted to read what you were referring to. And as I'm doing right now on my computer, doing a word search of 15.4 and 17.2, it doesn't find either one. So I was kind of lost on where you were getting this data from.
We can look during one of the breaks. There's no other point I'm trying to make. It's just I didn't see it. I'm not finding that from the article.
A. It may have been a typographical -- I may have misput it. It may not have made it --
MR. WALKER: Let's look into it at a break and close the loop on the record.
MR. RESTAINO: Sure.
Q. Okay. Then one of the -- when you support -- for support of your expert opinion that large failure rates from native tissue repair of pelvic prolapse exist, you cite Benson, Benson, Lucente and McClellan. The title is Vaginal Versus Abdominal Reconstructive Surgery for the Treatment of

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Pelvic Support Defects: A Prospective, Randomized Study with Long-Term Outcome Evaluation.
A. What number is that?
Q. What number as in --
A. What's the reference number? I'm sorry. Where are we looking? I'm sorry. I missed that.
Q. Okay. Give me one second and I'll find that for you. Paragraph 1 -- I'm sorry -- reference number 1 on page 3.
A. Oh, I'm sorry.
Q. On your expert report.
A. Okay. You're going back to page 3. All right. I'm sorry. I was still on 8. Say that again.
Q. Yeah, I flip around. So it's reference number 1 --
A. Right.
Q. -- of your expert report on page 3.
A. This is Benson. Gotcha. I'm sorry. I was back on 8. About the lifetime risk of pelvic --
Q. Yeah. You utilize that at the top of the page where it's referenced and where you're writing:
"After that I became interested in the vaginal approach to pelvic prolapse

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and realized the significance
for augmenting the repair
because of the large failure
rates from native tissue
repair."
Reference number 1, which is the Benson, et al., study.
A. Right.
(EXHIBIT 10 WAS MARKED FOR IDENTIFICATION.)
BY MR. RESTAINO:
Q. So I just asked her to mark Benson as number 10.
A. Yeah, I have it.
Q. Do you recall how you found this study?
A. I trained with Dr. Lucente. That's who actually taught me pelvic -- and I saw that -- he used to -- when I'd go to train, he would present. And he would always present studies and data. So he would talk about this. That's why I knew about this study.
Q. Okay. If you look at the study and on the abstract the study design, it starts off by staying "88 women."
A. Uh-huh (positive response), cervical

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prolapse beyond hymen.
Q. Yes. So would you consider this a small, medium-size or a large study?
A. I think under 100 -- I think 88 is probably a medium size.
Q. Okay. And then in the middle of that paragraph it states that:
"Detailed pelvic examination
was performed postoperatively
by the nonsurgeon coauthor
yearly up to five years."
What is your understanding of the term "nonsurgeon coauthor"?
A. The RN, Elizabeth McClellan.
Q. Okay. So this was followed up for five years; correct?
A. Correct.
Q. Now, if you'll look at table 2 on the second page, Surgical Procedures Performed, and the fourth one down is needle suspension urethropexy; correct?
A. Yes.
Q. And that's an operation traditionally used for moderate to severe stress urinary incontinence; would you agree?

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A. It was a procedure done for stress incontinence.
Q. And then the next procedure performed underneath that is the Burch procedure; correct?
A. Right.
Q. And the Burch is also used for SUIs?
A. But it was done in the abdominal group, not in the vaginal group.
Q. What does that mean?
A. The procedure was done from an abdominal approach, the Burch was done. The needle procedure was done vaginally.
Q. Okay. And then there's a description of autologous sling urethropexy. Do you see that?
A. Autologous sling urethropexy; right.
Q. And that's also a procedure to treat SUIs; correct?
A. Correct.
Q. And then the final one down at the bottom is "other." And we don't know what that "other" is; correct?
A. Correct.
Q. And so we don't know if it's a prolapse procedure or an SUI procedure; correct?

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A. Correct; we do not know.
Q. Okay. And if you look at the table, "other" is both -- in the vaginal group there's three, and in the abdominal group there's seven, for a total of 10 other procedures.
A. Correct.
Q. So 10 of the 88 procedures, we don't know if they're a surgery for prolapse or a surgery for SUI; wouldn't you agree?
A. I would agree.
Q. Now, on the fourth page, which is page 1420 of the study, there's a comment. And the comment is:
"The women in this study are
representative of a tertiary
urogynecologic referral
practice, reflected by the
magnitude of the prolapse (46
percent had grade 4
prolapse), the presence of
combined defects, and 56
percent prior failed ...
rate."
Where I was confused is you were referencing this paper for your statement about the large failure

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rate associated with native tissue repairs; correct?
A. Uh-huh (positive response).
Q. But as we can see from table 2 of this study, many of the procedures were for SUI and not prolapse. The needle suspension urethropexy, 20 of them were 42 percent; Burch procedure, 13 -- the Burch procedure; the autologous sling urethropexy, SUI and then others.
A. But wait a minute. All of them had a vaginal repair. They also had slings. They had different types of stress incontinence procedures. 100 percent of them had sacrospinous suspension and colposacral suspension, 48 and 48 in the vaginal group. So those were the vaginal repairs. Do you see what I'm saying? So everyone had a vaginal repair. They had different types --
Q. In addition to the vaginal repair, they had surgeries for SUIs?
A. Right, correct. So that's what these other --
Q. That's what the other procedures are for?
A. Yes.
Q. Okay. Thank you for that. Now, from what I read on the fourth page at page 1420 in the comment,

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56 percent had prior failed surgery rate; correct?
A. Correct. Okay.
Q. And we discussed that when there's a second procedure, the failure rate is typically higher than in an initial procedure.
A. It may be higher.
Q. It may be higher.
A. It may be higher. The question is: Is that 56 percent prior failed surgery native tissue?
Q. And there's no way of knowing?
A. We don't know that. But that's what I -- we don't know that.
Q. So without knowing that, that's a form of bias in this study. You're relying upon this study to support your expert opinion of a large failure rate with native tissue, but some 10 of these 88, or 11 percent, we don't even know what was done on them, and 56 percent of these women had had a prior surgery.
MR. WALKER: Object to the form.
BY MR. RESTAINO:
Q. So would you agree that this may not be a great study for supporting an opinion as to the large failure rate with native tissue repair?
MR. WALKER: Object to the form.

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A. It's a nice medium-size study. That may be one caveat that doesn't show that. As somebody that's reading this and has had experience as a vaginal surgeon, I would suspect that the native tissue -- that the previous failure was a native tissue failure. And that, I believe, is how Vince would present it. But I don't have that in front of me. As I sit here, I can't document that 100 percent.
BY MR. RESTAINO:
Q. Okay. If you were submitting your expert report or an article for publication in the peer-reviewed literature discussing the study, wouldn't you question the fact that 56 percent of these patients had had a prior surgery? And how does that extrapolate out to women receiving native tissue repair who have never had a prior surgery, so they're pristine? In epidemiology, does the term "external validity" -- does this study even apply to women who have not had prior surgery who then undergo native tissue repair?
MR. WALKER: Object to the form.
A. I'm not sure -- ask that question again, please. I was looking at this. I apologize.
BY MR. RESTAINO:

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Q. If you were submitting a paper, your expert report, for example, for publication in peer-reviewed literature, would you make the comment in your paper that, while there's a large failure rate here, one should note that 56 percent of the participants had had a prior surgery, and these results might not extrapolate to a pristine group of women?
A. I gotcha. Yes, I understand your question. And yes, my answer would be that the second -- the second surgery doesn't necessarily mean you're going to have a higher failure rate. I couldn't put my finger on a study that says that. In my experience I haven't had that situation, but -- so that would be my answer. It would be nice to know for sure what type of procedure they had.
MR. RESTAINO: If you would go ahead and mark this now as 11.
(EXHIBIT 11 WAS MARKED FOR IDENTIFICATION.)
BY MR. RESTAINO:
Q. I'm going to hand you an article, Doctor. It's by a Patrick Dallenbach, D-A-L-L-E-N-B-A-C-H, titled To Mesh or Not To Mesh: A Review of Pelvic Organ Reconstructive Surgery. And it appears to have

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been published in the International Journal of Women's Health in 2015. Have you seen this article before?
A. I may have. I am not familiar -- is it in my list?
MR. WALKER: Yeah, I was going to ask counsel do you know if it's on his reliance list?
MR. RESTAINO: I think it is. I can check really quickly.
MR. WALKER: And I found that statistic from that Barber study.
MR. RESTAINO: Did you? In the study itself?
MR. WALKER: Yes.
MR. RESTAINO: Yeah. Okay. I'd like to see that. Because I went crazy trying to find it.
MR. WALKER: The author's last name is Dallenbach?
MR. RESTAINO: Yes. And it's not showing up in his general.
MR. WALKER: I don't think it's on the reliance list. It's not on your reliance list.
THE WITNESS: Yeah. I didn't think I had seen it.
BY MR. RESTAINO:

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Q. In doing a PubMed search for your articles that you were going to rely upon, the title of this is To Mesh or Not To Mesh: A Review of Pelvic Organ Reconstructive Surgery.
Is there a reason why you didn't include this?
A. I did not -- it didn't come up when I looked.
Q. Okay. If you look at the introduction on page 1, you see they start off by writing:
"Surgery for pelvic organ prolapse (POP) is common among women. The lifetime risk of undergoing at least one surgical intervention by the age of 80 was estimated to be between 6.3 and 19 percent, with 30 percent of women requiring reoperation for recurrence."
References 1 and 2.
"The prevalence of reoperation after primary pelvic reconstructive surgery

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reported in some articles was even higher (43 percent to 58 percent)."
That's consistent with your expert opinion regarding the large failure rates associated with native tissue repair?
A. It's actually a little higher --
Q. Than what you stated?
A. -- than what I stated.
Q. In fact, consistent with what you just said, on page 6 of your expert report, you wrote:
"Unfortunately it has been associated with high recurrence rates of 30 to 50 percent."
A. Right.
Q. Does that sound familiar?
A. Yes.
Q. Now, looking at the Dallenbach paper, if you look at the final three lines underneath Introduction, they write:
"Based on our clinical experience, we found that these high rates of

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recurrence were probably overestimated. The results of previous studies addressed both urinary incontinence and POP, thus overestimating the risk of reoperation for POP alone. After closer examination of the references cited in some of the articles, we found that the higher recurrence rates resulted from studies including genital prolapse after Burch colposuspension, which is not a primary POP surgery but an anti-incontinence procedure."
Reference number 9.
"The aim of this article was to review surgical treatments of POP and analyze the evidence for the use of mesh material in pelvic floor reconstructive surgery."

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And the discussion regarding including findings from Burch colposuspension, et cetera, that's exactly what we were discussing in the Benson article, which included POP repair but also the SUI repair.
A. Yes.
Q. And so therefore the recurrence rates cannot be determined with accuracy from those articles when there's the combination of procedures. Do you agree with that?
MR. WALKER: Object to the form.
A. Yeah. Unless they're both -- unless you're comparing both, the same things.
BY MR. RESTAINO:
Q. Correct.
A. Both of them are the same. Okay. This is a nested -- I'm not familiar with this study. It says it's a nested case control study, cohort of 1,800 women? How did they come up with this data? This is new to me.
Q. Well, we're going to go through it a little bit and hopefully it will answer it. You can take a look at this. As a matter of fact, they state -- the next page under True Incidence and Risk Factors for Reoperation of Surgically Treated POP on page 2 -- do

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you see that?
A. Yes.
Q. And if you skip down six lines they write:
"We conducted a nested case control study in a cohort of 1,811 women who were surgically treated for POP in our department over a 20-year period. We found that the incidence of POP reoperation was 5.1 per 1,000 women-years with a cumulative incidence of 5.6 percent and a mean duration follow-up of more than 11 years.
With reference 11.
"This is much less than the 30 percent to 50 percent risk previously described."
So first, this study involves 1,811 patients, not 88; correct?
A. Correct.
Q. And it looked at the patients over a 20-year period and not a five-year period like Benson;

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correct?
A. It says over 20 years, yes. And it's all the same surgeons? That's what I don't know. I'm not familiar. Is it the same surgeons doing the procedure on all these patients? Are these people all in Switzerland?
Q. That's my understanding from it. And they found a cumulative incidence of 5.6 percent, which would you describe that as a large failure rate?
A. 5.6 percent is not a large failure rate.
Q. And again, this study and this data is not in your expert report?
A. Correct.
Q. Then if you'll look at the bottom of this paragraph we've been reading, six lines up, they write:
"Corroborating our results, recent studies reported lower rates (between 1.5 percent and 13 percent) of reoperation for surgically treated POP and urinary incontinence."
Did I read that correctly?

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A. Yes.
Q. And then they have three references there, number 3 --
A. 12 and 13.
Q. -- 12 and 13. Now, the first one is the Clark article, which is your reference number 11 on page 6. Let's go ahead and mark this as the next, if you would.
(EXHIBIT 12 WAS MARKED FOR IDENTIFICATION.)
BY MR. RESTAINO:
Q. There you go, sir.
A. I have it.
Q. You've got it? Okay. Now, if you'll look at the abstract and the results in the abstract of the Clark study, they write:
"36 women underwent 40 cases of reoperation. By survival analysis, 13 percent ... underwent reoperation by 71 months. Having undergone previous pelvic organ prolapse and urinary incontinence surgery

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increased the risk of reoperation to 17 percent compared with 12 percent for women who underwent a first procedure (log rank P equals .04)."

Did I read that correctly?

A. Yes.

Q. Noting the increased risk of reoperation to 17 percent, would you agree that it would be more appropriate, more scientific, to compare studies that looked at only women undergoing their first procedure versus only women undergoing first procedure?

MR. WALKER: Object to the form.

A. What do you mean? That's apples to apples. You're trying to compare apples to apples. So first surgery versus first surgery. Because second surgeries make it more difficult.

BY MR. RESTAINO:

Q. Yes.

A. That would be -- in a perfect world, that would be great. I just don't know how you could do that.

Q. And in this study here by Clark, which is,

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again, I think your reference number 11, the reoperation rate was 12 percent for women who underwent a first procedure; correct?

A. Right.

Q. So that's a lot lower than the 30 to 50 percent that your expert report states.

A. Yes. Tell me -- I'm confused where we're going with this as far as -- can we go back to see where I said 30 percent?

Q. Yes, of course.

A. What page are we on?

Q. Page 6 of your expert report you write:

"Unfortunately it has been associated with high recurrence rates of 30 to 50 percent."

A. Yes. Okay.

"60 percent of the recurrences are identified at the same site. Unmasking an occult support defect causes 32 percent of failures."

Q. So this study by Clark, which you've referenced, they talk about the risk of reoperation is

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17 compared to 12 percent for women who underwent a first procedure.

A. Okay. When did I reference Clark? Show me that.

Q. I think Clark is number 11 on page 6.

A. So I referenced Clark for a different reason. So I'm just seeing here.

"Unmasking an occult support defect causes 32 percent of failures."

That's when I referenced Clark.

(A DISCUSSION WAS HELD OFF THE RECORD.)

A. Okay. Where are we? What was the question?

BY MR. RESTAINO:

Q. So, in essence, looking at the Clark study, which is your reference number 11 and which Dallenbach references, their reoperation rate for seeing women is 12 percent.

A. Right.

Q. That's a lot lower than your 30 to 50 percent range that you have in your expert report.

A. Except that there are studies that say there's a 30 to 50 percent -- let's see. Dr. Vincent, the 9 -- that's where I got that, American Journal of

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OB-GYN in 2004. Can we look at that?

Q. Of course. Of course. But while there are -- and I agree with you. I've read the articles that have failure rates 30 to 50 percent.

A. Right.

Q. But there are many articles -- and we're going to get some more of them -- that show the rate to be between 5 and 12 percent. Why are those articles not cited in your expert report?

A. Because of my experience. I have seen more -- higher recurrence rates than 5 to 10 percent.

Q. Have you had higher recurrence rates than 12 percent personally in your hands?

A. On my native tissue repairs? You know, that's a hard question. I don't think it's been that high. But, you know, there are some situations where -- you've got to look at everybody that does native tissue repair. Some are better than others and some have higher recurrence rates. I don't feel -- I felt like my recurrence rate was high enough that I needed to augment my repair. I'll say that.

Q. Now, we can put Clark away. I don't think we'll come back to it. But returning for a moment to the Dallenbach study, there were three references that

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we looked at, number 3, number 12 and number 13.
A. Gotcha.
Q. And number 12 is an article by Diez, D-I-E-Z - I-T-Z-A.
A. Right.
Q. And it's titled Risk Factors for the Recurrence of Pelvic Organ Prolapse after Vaginal Surgery: A Review at Five Years after Surgery.
A. That's not on my list, is it? I don't remember that study, but it may be in my list.
Q. Okay. I don't recall. Let's go ahead and mark it.
(EXHIBIT 13 WAS MARKED FOR IDENTIFICATION.)
BY MR. RESTAINO:
Q. No, it's not coming up in your general.
A. Yeah. I didn't think it was.
Q. So if you'll just take a look at this one briefly. And if you'll turn to page 1320, they have a section titled Results. Do you see the upper right? They start with Results?
A. Yes.
Q. "Five years after surgery, 42 of 134 (31.3 percent) women

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presented anatomical criteria of failure in one or more compartments. None of the patients without anatomical recurrence were symptomatic. Only 10 of the 134 (7.4 percent) had functional surgical procedure."
Can you explain to the court what is your interpretation of what the authors mean when they say functional surgical failure?
A. That they were not symptomatic.
Q. Okay. So in this study by Diez-Itza undergoing POP surgery, there was a 92.6 percent functional success rate at five years; correct?
A. 10 had a functional surgical failure.
Q. Yeah. So I just took the 7.4 from 100.
A. Yes.
Q. So that's a functional success rate at five years of 92.6 percent.
A. In this study I would say that's what the results are, yes.
Q. That's what the results state in this?
A. Correct.

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Q. This is a paper that's not in your expert report or General Reliance List?
A. I don't think it is.
THE WITNESS: Jordan, I don't think it is.
MR. WALKER: I didn't see it on your reliance list.
BY MR. RESTAINO:
Q. And stating the obvious, 7.4 percent is lower than 30 to 50 percent; would you agree?
A. Yes; you're right. But I also talked a little bit about functional recurrence. It depends on the patient's symptoms. And, you know, that has to do with interpretation. And, you know, I don't know the details, and I haven't read this study to know the details of who's asking the questions. Was it because of a survey that they did or one of these repair -- I can't think of the word right now off the top of my head. You know, the PISQ scores or whatever when they ask these kind of questions.
Q. Yes.
A. Or is it somebody examining them in the office and they talk about what's going on? Or was it a phone interview? Those kinds of things. And that's what I don't -- I'm not familiar with. Because that

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can sometimes -- when you talk about functional repair, the way you ask a question sometimes can make a difference.
Q. Yes.
A. I did mention previously, though, we don't want to make them have a problem they don't have.
Q. Understood. But this paper, for however they diagnosed functional surgical failure, they have a 7.4 percent failure rate?
A. That's correct. According to this paper, that's what it says.
Q. Reference number 13 that Dallenbach puts to support their experience with lower failure rates is a paper by Price, et al. I'll go ahead and mark this as next.
(EXHIBIT 14 WAS MARKED FOR IDENTIFICATION.)
BY MR. RESTAINO:
Q. This paper is titled The Incidence of Reoperation for Surgically Treated Pelvic Organ Prolapse: An 11-Year Experience.
Are you familiar with this paper?
A. No. Is it referenced? I don't think so.
Q. I don't believe so either. If you'll look

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at the second page, study design, this is:
"An 11-year retrospective audit conducted of women who had undergone surgery for pelvic organ prolapse between 1995 and 2005 at a large teaching hospital in the UK."
Did I read that correctly?
A. Yes.
Q. And then in the results down below:
"During the study period, 2,099 women underwent surgery for pelvic organ prolapse. Of these women, 142 underwent a second operation for prolapse and 13 a third. The overall cumulative rate of reoperation following surgery for pelvic organ prolapse was 10.8 percent at 11 years following the initial procedure."
Now, just looking at this study, comparing it to the Benson study that you're relying upon, we've

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got 2,099 patients here; we had 88 patients there. Would you agree?
A. Yes.
Q. And Benson had a five-year follow-up ; this study has an 11-year follow-up, which is more than double; correct?
A. Correct.
Q. And if we take their failure rate, subtracting from 100, this has an 89.2 percent success rate; would you agree?
A. Yes. I've never seen -- this is the only study I've ever seen with this kind of success rate.
Q. You know, this study is not in your General Reliance List or your expert report.
A. Correct.
Q. Is there a reason why?
A. I never saw it come up.
Q. The last two studies showing 7.4 percent reoperation rate and 10.8 percent utilizing native tissue, is there a reason why this is not quoted in your expert report?
A. Because you've given me two studies, and I've got lots more studies that show you have a lot higher failure rate with native tissue.

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Q. Did you cherrypick only the studies that support your opinion that it's between 30 to 50?
MR. WALKER: Object to the form.
A. I did not cherrypick. I did not have these two studies.
BY MR. RESTAINO:
Q. If you were writing your expert report for publication in the peer-reviewed literature and you conduct a PubMed search, knowing that these studies exist, would you now include them?
A. I like to get the most data I can have. We're going to have studies that are outliers both ways, and I think the majority of the studies need to be reasonable and well done.
Q. Now, we'll talk in a general sense away from studies for a moment about the vagina.
A. Yes.
Q. Stating the obvious, as an expert gynecological surgeon, you have an understanding of the biomechanical forces present in the vagina; correct?
A. Correct.
Q. Reading about this, I read that there's an active and a passive component. Are they terms that

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you're familiar with that you utilize?
A. I don't use those terms.
Q. Perhaps in the context of what I was using -- and if they're not terms that you use, we can use your terms. Or if you say you don't understand it, we'll move on.
A. Gotcha.
Q. But I read that the active properties of the vagina are critical to maintain healthy sexual function and provide structural integrity in the vagina's central role in pelvic organ support. The active properties require energy to function.
That sounds --
A. That sounds like that's a good definition.
Q. Okay. And this is mainly served by the smooth muscle of the vagina?
A. Smooth muscle? Okay. Yes.
Q. The smooth muscle component.
A. Right.
Q. The passive properties of the vagina perform in the absence of any active force generation and are provided by vaginal collagen, elastin and matrix proteins. Sounding familiar?
A. That sounds familiar. That's fine. Filling

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the bladder would be a passive expansion of the vagina.
Q. Okay. Now, in early 2002 it's your opinion that Gynemesh PS was the best mesh available and it became your mesh of choice; correct?
A. Yes. After I had failures with Pelvicol.
Q. And who makes Pelvicol?
A. Bard.
Q. Is it still on the market?
A. I think they have Pelvisoft or something like that. I had failure rates with that. I think people -- we would find -- it would disintegrate and have complete failures afterwards.
Q. Now, Gynemesh is a sutured mesh placement as compared to the mesh kits; is that correct?
A. Well, it depends. Yes. You would tack it in sometimes, suture, sometimes we'd just lay it in there without any tension. But the mesh kits had arms and straps that you were definitely without tension.
Q. And you utilize Gynemesh today?
A. No, I don't anymore. Now I use a cadaver fascia, allograft, Axis Dermis. It's a coloplast product. I use that for my repairs. I still use slings. I still use TVT and TVT-O, TVT-Exact. And

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then I use a single side from coloplast called the Altis sling, A-L-T-I-S.
Q. Now the cadaveric mesh or cadaveric support that you use, just for the court or for the lay people who may be reading this, that's different from the patient's own tissue, say, from the fascial lata?
A. Correct. I did not use autologous fascia.
Q. So autologous comes from the patient's body?
A. Gotcha.
Q. Cadaveric comes from someone else's body?
A. Yes. But it is not -- it's human.
Q. Yes. Okay. And have you conducted any type of analysis as to the success rate you're experiencing now with cadaveric tissue versus when you used Gynemesh PS or Prolift+M?
A. I don't have any data to support that. But I've had good results in the last year since they took Prolift off the market.
Q. Understanding that your sole data is anecdotal but clinical experience is still some form of evidence, are you testifying now that you've not seen a big dropoff of success since you've switched to the cadaveric tissue?
A. I have not had big failures. I don't feel

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like I've got a lot of failures.
Q. Fair enough.
A. And all these anecdotal things I have is all I have.
Q. Sure. Now, what is your understanding when the medical literature, scientific literature, discusses the stiffness of mesh?
A. I would say its pliability. When you use it in your hands, you can tell. Unless you've been around the mesh and know exactly, you can tell the differences in the soft meshes and the medium-weight and light-weight and stiff meshes.
Q. Okay. Now, do you have an opinion as to the importance of the stiffness of mesh once it's placed inside a woman?
A. I think at least a medium-size mesh, you need a soft -- it needs to be supple to use in the vagina.
Q. Okay. Why is that?
A. Because of the forces that change when patients move, passive forces as well as active forces, if we're going to use that terminology.
Q. Okay. If I'm understanding you correctly, then the softer mesh would be more consistent with the

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normal anatomy of a woman?
A. Well, it's hard to say. I feel like you don't -- that the pore size is the ticket. And most meshes with larger pore sizes are softer meshes. The narrower -- the more smaller pore size is associated with a little stiffer mesh, in my opinion, feeling it.
Q. Okay. Are you familiar with the term "stress shielding" as used with mesh in the body?
A. No, I'm not.
Q. Okay. Are you familiar with the concept of when mesh is placed -- or any structure is placed against human tissue, if that stress -- I'm sorry -- if that mesh or structure has stronger strength than the human tissue, the human tissue will be shielded from forces and atrophy?
A. I have not known -- I have not seen that.
Q. Let me bring you back perhaps to medical school and your first year of internship. A great example of what I was reading and I came up with is cast atrophy.
A. I see.
Q. If we put a cast on a child's arm because he breaks his arm playing football, or she, when you take the cast off, you look at the two arms, and one is

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skinnier than the other.
A. Right.
Q. And that's because the muscle and the bone has actually atrophied because the cast has shielded that tissue from stress.
A. I see. I understand the concept. The difference with vaginal mesh, in my opinion, especially with the larger pores, is that tissue gets incorporated into the mesh and becomes -- you cannot feel the mesh inside. You cannot feel -- there's not -- the vagina feels normal. You can't tell if the mesh is in there. But it strengthens -- the prolapse is gone.
Q. Okay. Now, when you were first introduced to Gynemesh PS, did you ask or were you given clinical trials that were conducted with controls to look at the success rate of Gynemesh PS versus any other mesh or native tissue?
A. I was given some information that showed that mesh was superior to what I was using at the time, which was the porcine Pelvicol. The problem was I started putting it in incorrectly. In those days what would happen is we would dissect the posterior -- or anterior vagina off and we would reapproximate it

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in the pelvic fascia. And then we'd lay porcine graft on top of it and then cover it up. We were not getting full thickness vagina.
So when I started using Gynemesh, I did the same thing. I just put in Gynemesh and I had exposures. So after the first couple and I had exposures, I talked to the Ethicon folks, and I said: This is not acceptable.
So that's when I was flown to -- I went to Dr. Lucente in Allentown and learned you had to have full thickness and use dissection in the appropriate way to place the mesh. And after that it was all it took. And then I didn't have any exposures or minimal exposures and it was much better.
Q. I think that's a great example of one of my favorite sayings that I used when I was a residency director for three years, and I would turn to the residents in teaching and explain to them or say to them: Experience is that thing you get right after you needed it.
A. Right, right; that's correct.
Q. Okay. So when you were given the Gynemesh PS and then you talked with the representatives of Ethicon and you met with Dr. Lucente, et al., did you

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also review the instructions for usage?
A. Yes.
Q. And what is that?
A. The IFU?
Q. Yes.
A. Just the information they give on how to use the mesh, how to place the mesh.
Q. And you actually write in your report that it's your opinion that the IFU was more than adequate and helped surgeons use the devices safely; does that sound familiar?
A. Yes. And I was talking more about the Prolift, not just the Gynemesh. The Gynemesh IFU, I do not remember reviewing that as much.
Q. Okay. Do you know if you reviewed the Gynemesh PS IFU at any time?
A. I will know it if I look at it. Seriously, I don't remember. Like I said, I was using Prolift.
Q. Do you know if any of the IFUs describe mesh shrinkage?
A. They talk about tissue around the mesh shrinking, healing, in the process of healing. But not certainly mesh shrinkage.
Q. Okay. Have you seen -- have you seen --

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have you been shown -- are you familiar with the name Axel Arnaud, A-R-N-A-U-D?
A. No. Is he a urologist in Houston?
Q. He's from Ethicon. He's with Ethicon. Do you recall at all seeing an email dated July of 2004 where he suggested adding, quote, unquote, "mesh shrinkage as an additional adverse reaction in the Prolift IFU"?
A. I do not remember that.
Q. Do you recall any type of follow-up email from a Sean O'Bryan from Ethicon regulatory affairs who states:
"If mesh shrinkage is a real issue, we have an obligation to put it in"?
A. I'm not familiar with that.
Q. Would you agree that if a company selling a mesh device recognizes that they have an adverse event, which is mesh shrinkage, whatever is causing the mesh --
A. Correct.
Q. Because we'll talk about it in a moment. But if left alone, mesh is just an inert object. It's not going to shrink in the rain; correct?

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A. Right, exactly.
Q. But if scar tissue contracts and decreases the length, the width -- the length and thus the area, the mesh has shrunk; correct?
MR. WALKER: Object to the form.
A. Well, I will say if that were an issue, in my personal observation, then it would have been a big problem, I think. But I did not -- I did not have that experience that the mesh -- I mean we knew that the skin would retract around it, but we did not know anything about mesh retracting.
BY MR. RESTAINO:
Q. No one from Ethicon discussed with you that --
A. You know, I went to the launch meetings for Prolift and I went to lots of meetings with Prolift and we talked about lots of things. But I never remember thinking that was a problem, and they never brought it up as a problem that I know of, that I remember.
Q. And if you weren't seeing it in your own hands, in your own women, then would you agree you would have no basis for thinking it was a problem?
A. Yeah. I never thought it was a problem from

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my experience.
Q. And so no one at Ethicon told you we're having an issue, we're getting multiple reports of mesh shrinkage, we're thinking about adding it to the IFU; what do you think?
MR. WALKER: Object to the form.
A. They did not ask me that. And no one came to me and said: Are you having problems with this? I could not say I had.
BY MR. RESTAINO:
Q. And have you been shown anything from anyone at Ethicon regulatory affairs saying that if the new adverse reaction is added to the Prolift IFU, we will have to add it to the Gynemesh PS IFU also?
MR. WALKER: Object to the form.
A. No.
MR. RESTAINO: Okay. Let's take a break.
(A RECESS WAS TAKEN FROM 11:28 A.M. TO 11:34 A.M.)
BY MR. RESTAINO:
Q. Now, page 8 of your expert report at the top you write:
"Native tissue repairs present a potential risk of

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bleeding, organ damage (e.g., bladder, bowel, urethra, ureters), nerve damage, urinary frequency, dysuria, incontinence, urinary retention, urgency, acute pain, chronic pain, scarring, acute and/or chronic pain with intercourse, infection, neuromuscular problems, wound complications, fistula formation, recurrent prolapse, prolapse in an unrelated compartment, contraction or shrinkage of tissues, and a foreign body response."
Did I read that correctly?
A. That was a long sentence.
Q. Now, every one of these also occurs -- can occur with mesh procedures; correct?
A. Any type of vaginal surgery for repair of prolapse. All these are related. All of these are possibilities. Let's put it that way.

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Q. So you're not telling the court here that these complications are unique to native tissue repair and that their incidences are greatly reduced by using mesh?
MR. WALKER: Object to the form.
A. Say that again.
BY MR. RESTAINO:
Q. That was a lousy question. So when you state here that native tissue repairs present, you're not trying to tell the court look at all these complications that are associated with native tissue repair; they don't exist with mesh surgery?
A. That's correct. I'm not saying that.
Q. Okay. And not only can any of these occur with mesh, but mesh adds the component of the potential for mesh extrusion?
A. Exposure.
Q. Exposure?
A. Don't forget my word. Yes, mesh exposure. That's exactly right. The point is this vaginal surgery has its own inherent risks. And those risks are the same. And when mesh is added, there is a potential for mesh exposure that native tissue doesn't have. Suture exposure possibly if you use permanent

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sutures but not mesh exposure.
Q. With today's use of cadaveric -- I'm sorry. Is it cadaveric fascia?
A. Yes.
Q. -- do all these potential complications exist?
A. They exist but no exposure. I have not had an exposure yet from cadaveric fascia.
Q. Now, on page 24, paragraph O --
A. 24 of my report?
Q. Of your report, yes. I'm sorry.
A. Okay. O?
Q. O.
"Mesh exposure is the only unique complication with Gynemesh PS and Prolift ..."
Do you see where I'm reading from?
A. No. I have L, M, N. I don't have O for some reason.
MR. WALKER: What page of the report?
THE WITNESS: He said 24.
MR. RESTAINO: I thought it was on 24. Let me check.
THE WITNESS: It's on 26. Okay. Here it

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is. "Mesh exposure is the only unique complication." Gotcha.
BY MR. RESTAINO:
Q. Okay.
-- "complication with Gynemesh PS and Prolift, although as noted above, other complications occur without the use of mesh."
A. Yes. Reference 60.
Q. And what do you mean when you use the word "unique"? You write it's unique --
A. Because it's mesh compared to something where you don't use mesh. Native tissue doesn't use mesh. Mesh you use mesh.
Q. Okay. Then on page 39 -- hopefully I wrote the page correctly -- of your report, you write that:
"Mesh shrinkage or contraction is discussed in the literature" --
Do you see that?
A. Uh-huh (positive response).
Q. -- "but is somewhat of a misnomer. Scar tissue does

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shrink or contract during the healing process, and the scar tissue that is incorporated into the Gynecare pelvic organ prolapse products is no exception, but the mesh itself does not contract or shrink."
A. Right.
Q. So as we've discussed, you agree that any surface reduction, if there is any, of the mesh is not due to the mesh itself physically contracting but the forces of the body contracting the mesh?
A. The scar -- the patient's native tissue.
Q. Okay. And have you seen articles at all that discuss the mesh experiencing as much as a 20 to 50 percent reduction in initial size?
A. I have seen articles like that, but I have not seen that clinically to be an issue.
Q. You haven't seen it in your patients?
A. In my patients; right.
Q. But you're familiar with it?
A. I'm familiar with it in that I've seen articles.

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Q. If in fact Ethicon as early as 2005 is aware of a 20 to 50 percent contracture or shrinkage of their mesh, in 2005 we're talking about --
A. Just starting Prolift.
Q. Don't you think that's something that they should be making physicians aware of?
MR. WALKER: Object to the form.
A. Here's my idea about that. It's still -- the mesh itself is not contracting, but the scarring causes some retraction of the skin around it. But the mesh -- you can't feel the mesh inside the vagina. It's not -- well, in my experience, it was not clinically significant. So I would say that the company didn't need to report that unless they knew for sure they had real data that could confirm that it lost 50 percent, contracted 50 percent. In other words, is your vagina going to be half the size it is because of contraction? And that just does not happen.
BY MR. RESTAINO:
Q. Okay. I'd like to show you an article that we'll have marked as 15. And this is by William Cobb, et al. It's titled The Argument for Lightweight Polypropylene Mesh in Hernia Repair.

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(EXHIBIT 15 WAS MARKED FOR IDENTIFICATION.)
BY MR. RESTAINO:
Q. Does this article look familiar to you?
A. It does not, but I've looked at lots of them. Oh, this is one that has Monocryl in it as well. This may be on my list.
MR. WALKER: There it is right there.
A. Yes. And I note granuloma and porcine isn't on this.
BY MR. RESTAINO:
Q. So you've seen this article before?
A. I recognize this article, yes.
Q. And if you look at the top of the very first page, you'll see that it was published in 2005.
A. Yes.
Q. And it's published in the journal Surgical Innovation. Is that a journal that you would subscribe to?
A. No.
Q. Do you know any gynecologist who subscribes to Surgical Innovation?
A. Not that I know of.
Q. Okay. If you look on page 67, in the upper

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right there's a section titled Degree of Shrinkage. And they write:
"One concern with the long-term implantation of mesh is the amount of shrinkage or passive compression the material undergoes. All available meshes, regardless of their composition, experience a 20 to 50 percent reduction in their initial size. Factors of the mesh itself and the surrounding issue of inflammatory response contribute to this phenomenon."
Did I read that correctly?
A. Yes.
Q. So is it fair to say that in 2005, while you as a gynecological surgeon may not be reading Surgical Innovation, Ethicon as the manufacturer of mesh is on notice that all meshes are undergoing a 20 to 50 percent reduction in initial size per the report from

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this article?
MR. WALKER: Object to the form.
A. You know, I see -- yes, that's exactly what this says. I would love to see how they came up with these numbers.
BY MR. RESTAINO:
Q. Okay. And by numbers, you mean how they're quantifying it?
A. Yes.
Q. Okay. We're going to get to that. Is it fair to say, Doctor, that when you were a preceptor in 2005ish or so, that you weren't sharing with the attendees that the mesh was undergoing this degree of contracture because you weren't aware of that?
MR. WALKER: Object to the form.
A. I was not aware of 20 to 50 percent reduction; correct.
BY MR. RESTAINO:
Q. Okay. We can put this one down for a moment. And perhaps, if I remember correctly, this one will assist in quantifying the shrinkage. If we can mark this one. This is 16, an article by Miguel Angel Garcia-Urena, U-R-E-N-A, titled Differences in Polypropylene Shrinkage Depending on Mesh Position in

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an Experimental Study Published 2007 in the American Journal of Surgery.
(EXHIBIT 16 WAS MARKED FOR IDENTIFICATION.)
BY MR. RESTAINO:
Q. I did not find this report in your General Reliance or Supplemental Reliance. Do you recall seeing this?
A. I do not.
Q. If you turn to page 540 of this study --
A. This is the rabbit study; is that right?
Q. It's a rabbit study.
A. Yeah. This is a rabbit study. That's what I meant. I'm sorry.
Q. I was confused for a minute if you meant that 14-day study we talked about earlier.
A. No.
Q. If you turn to page 540, there's a table 3. And then right underneath table 3 on the left there's the first paragraph with the data in it.
A. Correct.
Q. And you see in table 3 they write:
"The two-dimensional examination showed a

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significant shortening of the mesh in length and width on the 30th day" -- with the P values there -- "the 60th day" -- again with P values -- "and the 90th day" -- with P values. "The implant areas were reduced by 25.92 percent" -- and then there's differences for the onlay or sublay positioning in the hernia repair -- "on the 30th day, by 28.67 percent ... on the 60th day, and by 29.02 percent ... on the 90th day."

And at the very, very last sentence of the paper --

A. Last sentence of the paper?

Q. Of the paper. It's actually the last paragraph.

A. Yeah. "We conclude"?

Q. "We conclude that polypropylene meshes undergo

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an important degree of shrinkage that occurs during the scarring and remodeling process. In this experimental model, this shrinkage has been smaller when the biomaterials were implanted in the sublay retromuscular position than when they were placed using extrafascial onlay technique."

Now, did Ethicon ever share with you similar experimental studies with mesh taken out of women?

A. I did not see any meshes -- any reports like this. But when we're talking about sublay and overlay, you're talking about sublay is underneath full thickness and one is extrafascial?

Q. Yes.

A. Sublay was better than the onlay.

Q. In the hernia repair?

A. In the hernia repair. Gotcha. That's what I wanted to make sure it said.

Q. So in just looking -- or glancing through the study, they remove the mesh, and then they measure

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the width, length, and then -- with width and length, of course, they can determine area. And they come up with numbers that are just below the 30 percent that's been referenced.

A. The problem with it -- the only problem that I can see with it -- and I'm not an expert. I'm not a bench scientist. But getting the mesh out puts pressure on it some to get it to -- to remove it. And then to start measuring it, I think it may change it some when you do that versus what it is in vivo. And I've seen data where the slings were measured with ultrasound data that showed that the sling didn't change in length. The amount of length in the sling was the same by ultrasound. So there was no shrinkage in the mesh itself.

So that's the data I'm using. That's my thinking about it. When you have to remove the mesh, if it changes and gets distorted, that's a different problem. It changes it up some.

Q. Now, I have some questions about that later, but we can jump to that right now. First, correct me if I'm wrong. I thought you said that you've not personally removed an entire mesh.

A. No. But I've removed -- no. You're right,

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I haven't. I'm just saying I would think -- I've removed some mesh. And when I see the mesh as I'm dissecting it out, it's different than when I get it out. Does that make sense? Because you have to pull and tug to get it to come out. I will say it's important when you talk about explanting mesh that the pore sizes seem the same. When you get in there, it's not like it's collapsed on itself, in my experience, especially the ones I've removed that I put in. But I've had to remove or explant meshes that other doctors have put in, and I didn't see that either as well. The pore sizes are the same. It's not that it wasn't exposed, but it didn't look like it had been distorted, is my opinion.

Q. Okay. Now, if you can walk us through the excision of the mesh. I was visualizing it that when you're grabbing the tissue, you're grabbing it with forceps perhaps?

A. Yeah. Usually it's pretty -- you know, it's incorporated in the tissue. So you're dissecting it out. So you're putting tension on one side and pulling on the other side.

Q. So with a 10 blade or whatever you're cutting with?

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A. Right. And then you're cutting, and then you maybe have to use a Kelly Metzenbaum, you have to use a Kelly clamp to pull to get it to separate as you dissect it out.
Q. Now, in deposing some of the experts for Ethicon over the last couple of years, I've heard that several times: Well, we don't know if the forces from excision has actually led to deformation of the mesh versus the shrinkage itself.
A. Correct. I understand.
Q. Now, the question that I have in that regard in talking with experts on our side, have you ever been able or have you read of anyone who's actually quantified what the force is in excising mesh comparing it to the force on that mesh from going upstairs, from having sex, from riding a bicycle?
A. I have not seen that. But I just know that the mesh, taking it out, is a lot more than -- excuse me. The force on the mesh taking it out is a lot more than when you put it in. Putting it in is very -- it does not take much energy to put it in. Does that make sense?
Q. Yes, yes.
A. Especially with a cannulus and all that kind

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of thing. When you use cannulus to put it in, you can lay it up there very easily. You don't have to push and tug at all on the mesh. And that's the goal, that's the idea. But when you remove it, you've got to put a lot more force getting it out. That's all I'm saying.
Q. Okay. Trying to put a period then on this topic, though, do you have any objective data that shows that the forces associated with careful dissection and excision exceed the forces on the mesh that exist in vivo in the woman as she's living her life?
A. I don't have any data to support that. But I would think, just in my -- I'm going to make a conjecture that the forces in life are less than what we have to do to pull it. Because I have experience taking it out, and it's a procedure.
MR. RESTAINO: Okay. Is this a good time to break for lunch?
MR. WALKER: Sure.
(A LUNCH RECESS WAS TAKEN FROM 11:54 A.M. TO 12:49 P.M.)
BY MR. RESTAINO:
Q. Okay. I want to now mark next -- when we

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left off, we were talking about mesh contraction --
A. Correct.
Q. -- and what was known in '05 and what was shared with you as a preceptor that you could share.
And I'd like to have this one marked as 17.
(EXHIBIT 17 WAS MARKED FOR IDENTIFICATION.)
BY MR. RESTAINO:
Q. And this article, Dr. Shoemaker, is from 2010, Vaginal Mesh Contraction, Definition, Clinical Presentation, and Management by Feiner and Maher. Do you recall seeing this article?
A. I don't know. I don't think -- is it on my list? I don't think it's on my list. I know Maher, but that's part of the Cochrane review.
Q. Yeah. I'm not finding it, and I didn't find it in your General Reliance document. And yes, I noticed also that Christopher Maher is the lead author of the two Cochrane studies.
A. Right, right. Okay.
Q. One part about this for me -- you might disagree. If you'll look under methods of the abstract, the first page:
"This is a case series of

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women who underwent surgical intervention ..."
Stopping there only because the prior article where we left off talked about, as you pointed out, a rabbit study.
A. Right.
Q. And just wanting to obviate you turning to me and saying, John, you're limiting this to rabbits, I want to bring a human study into it also.
A. Okay.
Q. So if you would look at page 326 of this article by Feiner and Maher --
A. Let me say real quick this is 17 -- wait a minute; is that correct? 17?
Q. I believe so, yes. So I'll go on and say, one, this is a case series. So there isn't a control group. They're looking at tissue. And it is limited to 17 women.
A. Correct.
Q. Okay. With that in mind, if you'll look at the first full paragraph of the left column on page 326, it starts:
"While in vivo shrinkage of polypropylene mesh up to 50

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percent of its original size has been previously demonstrated both in animal models and in women, the clinical implication of this bioclinical characteristic remains undefined."

And the shrinkage of 50 percent original size, you don't discuss that in your expert report; correct?

MR. WALKER: Object to the form.

A. Right.

BY MR. RESTAINO:

Q. And I think before we left off, I either thought of asking you or I did ask you that when you were talking to the preceptors for the Ethicon-based programs, you weren't given information regarding the shrinkage rates that Ethicon was aware of at the time, were you?

MR. WALKER: Object to the form.

A. I'm not sure what they were aware of, but I was not told.

BY MR. RESTAINO:

Q. Okay. Now, if you look at the conclusion of

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the abstract of this study by Feiner and Maher, they conclude that:

"Vaginal mesh contraction is a serious complication after prolapse repair with armed polypropylene mesh that is associated with substantial morbidity, frequently requiring surgical intervention. Research and development is urgently needed for new graft materials with diminished shrink properties."

Did I read that correctly?

A. Yes.

Q. Now, was the issue with shrinkage that you experienced to whatever degree in your own patients -- did that play any role in your going on to using cadaveric grafting today?

A. No, not shrinkage.

Q. Does cadaveric fascia shrink also?

A. I'm not aware of any and I've not seen any studies that say it does.

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Q. I haven't seen cadaveric fascia other than that which we dissected in gross anatomy. It doesn't have pores like mesh; correct?

A. It does not have pores.

Q. So now I'm just thinking out loud here. If the mesh contracture is being caused by in-growth into pores of tissue that then scars and contracts it, you wouldn't expect that to happen with cadaveric fascia, would you?

A. It's hard to say. It's hard to say how exactly it works and what the reaction is in the scar to the cadaver fascia. I have not seen it contract and make the vagina smaller like I haven't with my meshes as well.

Q. Sure. Okay. Based upon your review of the literature and not the excellent results that you have with your patients, do you have any objective basis to disagree with Dr. Feiner and Maher when they say that:

"Vaginal mesh contraction is a serious complication after prolapse repair with armed polypropylene mesh that is associated with substantial morbidity ..."

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A. I object -- I agree with the fact that in these 17 patients that they studied, that was what they found. I have not seen that, and I have lots of literature that says we don't feel like that's the case. But that's how I approached that.

Q. I want to take a look now at the Ellington study.

(A DISCUSSION WAS HELD OFF THE RECORD.)

(EXHIBIT 18 WAS MARKED FOR IDENTIFICATION.)

A. I may have this one. Is this on my list? I don't remember Ellington, but I know Holly Richter. She's in Birmingham.

BY MR. RESTAINO:

Q. It's not coming up on the General Reliance List.

A. I want to say I've seen this somewhere, but I don't remember exactly where.

Q. This is published in Obstetrics & Gynecology International; correct?

A. Right.

Q. And this is 2013. As you can see in the title, it's The Role of Vaginal Mesh Procedures In Pelvic Organ Prolapse Surgery in View of Complication

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Risk.
A. Correct.
Q. If you look at page 3, they have a paragraph 2.3. And there they have --
A. Mesh Contracture.
Q. -- Mesh Contracture. And they write in the first sentence:
"Another unique complication that is often associated with pelvic pain and perhaps a more morbid sequelae is mesh contraction ... or reduction in the size of the vaginal mesh implant that may lead to mesh prominences or strictures within the vagina."
And they reference 22.
Did I read that correctly?
A. Correct.
Q. And for the judge and/or jury, what is meant as a physician "morbid sequelae"?
A. Well, it looks like they're referencing the study we just talked about with 17 women for mesh

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contraction. It may not be, but it looks like that's where they're getting that data. But morbid sequelae would be something on there -- the patient exam and their complaint that was causing enough discomfort that they felt like they had to take her back to surgery.
Q. Okay. And in fact, you are correct. Their reference is for the --
A. 17 patients.
Q. For Feiner and Maher.
A. Ellington and Maher.
Q. No. Feiner and Maher. The one we just marked previously.
A. Oh, Feiner and Maher. Sorry. Sorry. You're right.
Q. While you have been -- while you and your patients, especially your patients, have been fortunate in your rate that you've seen of contracture, would you agree as a gynecologist that vaginal mesh contraction can be a serious complication that can be associated with severe vaginal pain?
A. If in fact the vagina has shortened or shrunk, which I have not seen personally, that could be a complication.

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Q. And is the shortening of the vagina as a result of mesh contracture from whatever cause -- can it be associated with dyspareunia?
A. I suppose it could. There are lots of reasons for dyspareunia. You could have a short vagina and that may cause discomfort.
Q. Okay. And can there be focal tenderness over the contracted portions of the mesh?
A. I'd have to do an exam to see. I don't know that.
Q. Looking at the Ellington study, the contracture with mesh is also a unique complication that you wouldn't see with native tissue; would you agree?
A. Well, you can get skin retraction and scarring without mesh. But if mesh was placed and you had that -- if the mesh was in place, then that could be associated with -- not with the mesh but it could be that the mesh is there.
Q. Okay. Because looking at the Ellington study, again that paragraph 2.3, Mesh Contracture, they start off by saying "another unique complication." And so do you read that as being a unique complication to mesh?

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A. Not necessarily. You could actually have that same complication without mesh there from a scarring of the vagina.
Q. Okay. I think we're done with both of those studies.
MR. RESTAINO: Would you go ahead and mark this as next in line.
(EXHIBIT 19 WAS MARKED FOR IDENTIFICATION.)
BY MR. RESTAINO:
Q. Doctor, I'm handing to you an article by lead author K-A-S-Y-A-N titled Mesh-Related and Intraoperative Complications of Pelvic Organ Prolapse Repair. Do you recall this study?
A. I do not recognize this Russian study.
Q. It is in your reliance list on page 21.
A. Let me look at it. Let me see where.
MR. WALKER: No, no, no. This is your tab for what you cited in your report. Your reliance list is going to have --
THE WITNESS: Gotcha. All right.
A. So it is cited in there?
BY MR. RESTAINO:
Q. Yes, it is cited in there.

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A. I don't remember. If I look in here, I may be able to tell.
Q. If you look on the first page under Introduction, about the ninth line down, sixth one up from the bottom of the first paragraph, there's a sentence that starts: "The most frequent complications" -- do you see that, sir?
A. Yes.
Q. -- "include vaginal mucosa erosion, mesh shrinkage, infections, pain, urinary tract disorders, and a recurrence of prolapse."
Did I read that correctly?
A. Yes, you did.
Q. So these authors are describing mesh shrinkage as one of the most frequent complications associated with mesh usage for POP; correct?
A. That's what this sentence states, yes.
Q. Do you disagree based upon your review of the literature that it's one of the most common complications?
A. I have not seen that as one of the most common. In fact, it looks like it says here .3

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percent or it's 1 percent. I'm trying to read what it says. It's a low number, it looks like. Out of 677 patients, it looks like it's a low number.
Q. Okay. If you'll turn to the fourth page, page 299. And they have a paragraph there titled Mesh Shrinkage.
A. Uh-huh (positive response).
Q. And they write that:
"Shrinkage of synthetic mesh after implantation is one of the most serious complications. It was registered in five cases in our study and was characterized by severe vaginal pain, dyspareunia, vaginal shortening, urethral obstruction, and prolapse recurrence. Surgical intervention is often required to alleviate symptoms."
Did I read that correctly?
A. Yes, you did.

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Q. Now, this paper is in your reliance list. But that information and the description of mesh shrinkage as being one of the most serious complications is nowhere in your expert report, is it?
A. Correct, correct. Because --
MR. WALKER: You can explain it if you want.
A. Let me explain that. It's talking about five cases in this situation. And I'm not sure how you get urethral obstruction with a mesh case that was put in correctly. And also it talks about the fixation arms. I'm not sure how this was placed that it would cause this kind of situation. Maybe if it was not placed tension free, maybe that caused some of the -- when it scarred, it made the contraction worse -- the scarring of the vagina worse and caused the pain. Because I don't know how you get a urethral obstruction from a vaginal mesh. I just don't see how that could happen, unless they put it in the urethra incorrectly. There's no way it could affect the urethra, in my opinion. In fact, the mesh shouldn't be placed that far. It should stop at the urethrovesical junction, so there shouldn't be any mesh near the urethra, unless it was from a sling. But it doesn't mention that.

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BY MR. RESTAINO:
Q. Okay. Now, the Gynemesh PS mesh that you started using in 2004, 2005 --
A. Probably earlier than that. Because I was using it, and I had probably been to Allentown a couple of times before. And in fact, the first time I went to Allentown must have been around 2002. And then I went the end of '03 or the beginning of '04 because he was doing Gynemesh and trying to work with like doing early Prolift that they were learning from France. And then December of '04 is when they had the first Prolift cadaver lab, and I was present at that one.
Q. Okay. But you had already been using it for some time?
A. I had already been using Gynemesh for some time.
Q. Do you have an opinion today as to whether the actual mesh itself within Gynemesh PS is a stiffer mesh than some of the later meshes; for example, Prolift+M?
A. I think it's a mid-weight mesh, mid-weight to light-weight. It's hard to tell the difference when you deal with it.

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Q. Okay. Would you describe it as high stiffness?
A. No.
Q. I want to show you an article by Feola, F-E-O-L-A.
A. Are we through with this one?
Q. Yes.
(EXHIBIT 20 WAS MARKED FOR IDENTIFICATION.)
BY MR. RESTAINO:
Q. Do you recognize that paper?
A. No.
THE WITNESS: Is it in my list, Jordan?
BY MR. RESTAINO:
Q. Yes, it is. It's on page 14.
A. Yes. Let's see. (Reading.)
Q. If you look at the abstract, the objective of it is:
"To define the impact of prolapse mesh on the biomechanical properties of the vagina by comparing the prototype Gynemesh PS (Ethicon) to two

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new-generation lower stiffness meshes, SmartMesh (Coloplast) and Ultrapro (Ethicon)."
A. And Ultrapro is Prolift+M; is that correct? Ultrapro?
Q. Now, if you'll look under results, it says:
"Vaginal contractility decreased by 80 percent following implantation with the Gynemesh PS (P equals 0.001), 48 percent after SmartMesh" -- again P value -- "and 68 percent after Ultrapro Parallel" -- P value -- "and was highly variable after Ultrapro Perpendicular" -- with a P value.
Leading to conclusions being:
"Deterioration of the mechanical properties of the vagina was highest following implantation with the

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stiffest mesh, Gynemesh PS.
Such a decrease associated with implantation of a device of increased stiffness is consistent with findings from other systems employing prosthesis for support."
Did I read that correctly?
A. You read it correctly.
Q. Are you seeing the same type of problems now in the vagina with the use of the cadaveric fascia with the effect on the contractility of the vagina?
A. Well, let me ask: How do they come up with vaginal contractility? That's what I was trying to see from this method.
Q. Okay. Let's take a look at the study itself.
A. I was trying to figure out how they determined contractility, if that makes sense.
Q. Yes. And if you look under --
A. It looks like it's an animal study; is that correct? Nonhuman primate model?
Q. Yes.
A. Rhesus monkeys. That's why I'm not sure

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about how they determined the contractility. That would be a hard thing for me to assess. I sure haven't seen that in my experience.
Q. Okay. If you look under -- on the page 226, as we had discussed earlier in the deposition about active properties and passive, you can see they describe here their methodology for determining the contractility.
A. Show me where does it -- I see these mesh -- they have two straps for anchored with sacral promontory versus tension free. So that may make a difference with it. I'm just not sure how we can apply it. I can't see how we can apply that necessarily to humans in the surgery -- in the experience that I have.
Q. Okay.
A. I'm not saying it didn't happen in this, but I can't see how it applies to me, to my patients.
Q. If you look at page 230, the last paragraph on the left, they write -- I'm looking at -- it's about the middle of the paragraph, lower left paragraph, almost the middle on the right-hand side. The sentence starts off with: "The evidence."
A. On the right side?

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Q. It's the left column.
A. Left column. Okay. "The evidence within this article," yes.
Q. "The evidence within this article illustrates that all meshes used in this study had a significant negative impact on the biomechanical properties of the underlying and incorporated vagina, but the degree of negative impact correlated with the weight and stiffness of the implanted mesh. Indeed, the prototype mesh, Gynemesh PS, the stiffest, heaviest mesh implanted in this study, had the greatest negative impact on both vaginal contractile (active) and passive biomechanical properties following implantation."
Now, understanding that this study is done in a nonhuman primate, do you have any evidence to

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suggest that their findings comparing the meshes is inaccurate?
A. No. I think the findings regarding the meshes in this study and these animals is accurate. I just don't know how we can extrapolate it to humans.
Q. Okay. Can you, without actually even extrapolating to humans, from this can you extrapolate that Gynemesh PS was the heaviest, stiffest of the three meshes?
MR. WALKER: Object to the form.
A. It is heavier. I'm not sure it's necessarily the stiffest. But it is heavier than the light meshes, yes, lighter-weight meshes.
BY MR. RESTAINO:
Q. Now, when you mentioned that you were invited to the cadaver lab launch of Prolift, who invited you?
A. Ethicon. I'm not sure exactly who -- how I got chosen.
Q. During the time did you teach anatomy and physiology of the vagina?
A. No. I was actually a participant. I was not one of the -- I was at the launch cadaver lab, but I was one of the ones being trained.

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Q. Forgive me. Later when you became a preceptor.
A. Yes.
Q. Then did you go around --
A. And did the cadaver labs, yes.
Q. And did you teach the younger --
A. Showed them how to place them, yes.
Q. Not necessarily younger but the less experienced surgeons anatomy?
A. Yes, I did.
Q. And then how to implant it?
A. Yes.
Q. The indications for using Gynemesh PS?
A. Yes.
Q. Did you discuss at the time contraindications?
A. I'm sure I did.
Q. Warnings and adverse events that were known to you?
A. Yes.
Q. Do you know or do you recall if the IFU for Gynemesh PS was handed out at the time?
A. I'm sure it was.
Q. And at that time did you know or did anyone

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share with you that the predicate device for Gynemesh PS was Boston Scientifics' ProteGen, P-R-O-T-E-G-E-N?
A. I'm not familiar with that. I mean I've heard of ProteGen, but I'm not sure -- I don't know if it was the predicate or not.
Q. Do you know that three years after it was marketed, ProteGen was removed from the market because of safety concerns?
MR. WALKER: Object to the form.
A. No.
BY MR. RESTAINO:
Q. Now, is it fair to say that the transvaginal mesh studies using -- you write:
"Transvaginal mesh studies using Gynemesh PS began in 2004 and reported data at six months."
I'm reading from page 11 of your expert report.
A. Okay. Page 11?
Q. Yes. I think it's the last sentence of 11:
"Transvaginal mesh studies using Gynemesh PS" --
A. Let me see here. Okay. I gotcha. Okay.

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"Transvaginal mesh studies using Gynemesh PS began in 2004 and reported data at six months. A later study presented data at one, three and five years."

Yes.

Q. Now, where was this data reported?

A. It looks like in the International Urogynecology Journal, Jacquetin. It's from the French. It's the Fritz study. They did original TVM.

Q. Was that an abstract?

A. No, no. What do you mean? It was a study.

Q. It is a study?

A. Yes.

Q. Oh, I'm sorry. I see. You're talking Jacquetin, and you quote as saying:

"A later study presented data at one, three and five years."

A. Right, yes.

Q. You first wrote:

"Transvaginal mesh studies using Gynemesh PS began in 2004 and reported data at six months."

And I was struggling with that.

A. I see what you're saying. Yeah, I think probably -- I'm not sure where this -- I think the original Gynemesh, when he started talking about this, it was originally a six-month data. And then later it was presented at one, three and five years. And I think it's all Jacquetin. I think it's all original French studies.

Q. As you sit here today -- and this isn't a memory test -- but do you recall where the six-month data was presented?

A. No. But I have it somewhere. No, I don't remember.

Q. Okay. Now, prior to the publication of the Jacquetin study, which we're going to get to next, in 2013, would you agree, based upon your review of PubMed and what you've been given, there wasn't any published data on the safety and efficacy of Gynemesh PS?

A. After when now, you said?

Q. Between 2004 and when Jacquetin published his study.

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A. Yeah. Because -- well, most of the data after that was on Prolift. Because now we were using the mesh kits for the repair, not just plain Gynemesh. I wasn't. I was using Prolift after that.

Q. Okay.

MR. WALKER: Counsel, I'm sorry to interrupt. I'm just confused.

MR. RESTAINO: Sure.

MR. WALKER: Are you suggesting that there were no studies reflecting data on Gynemesh PS?

MR. RESTAINO: Not that there weren't any studies published, but the six-month data --

MR. WALKER: You're just asking about the six-month reference?

MR. RESTAINO: If that's published -- if that isn't published somewhere, then what data was being shared with the people that were going through training?

A. I understand. I'd have to research that.

Q. Okay. So let's look at Jacquetin, which was published in 2013.

A. I think I have that here.

MR. WALKER: This is Exhibit what?

THE REPORTER: 21.

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(EXHIBIT 21 WAS MARKED FOR IDENTIFICATION.)

BY MR. RESTAINO:

Q. So if you look here on the abstract right column, do you see there they have a 16 percent mesh exposure rate for which eight resections were needed to be performed? Do you see that?

A. Yes.

Q. Now, this is the first time that -- strike that.

This is the first article I've been able to find preparing for your deposition where mesh exposure rates associated with Gynemesh PS was published. Do you have any other data?

A. I may have some other data. Because I know that 16 percent is a high number for mesh exposure. And when I was teaching it, we were not using 16 percent. And I'm not sure where that data is, but I have it somewhere.

Q. Okay. Would you agree that prior to this time, the IFU didn't contain this information?

A. The IFU did not. Well, I shouldn't say that. I'd have to look to make sure. I don't know that.

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Q. Okay. I haven't seen any --
A. I have not seen it. If I saw an IFU, I don't know for sure. I'd need to look at it.
Q. In fact, one of the things that I was struck by when I first started looking at the IFU is -- as a physician and surgeon, you prescribe medications?
A. Yes.
Q. Now, if there's a new medication, a new antibiotic or something new that comes out, do you read the product insert associated with it?
A. Usually.
Q. Indications, contraindications?
A. Sure. Black box warnings, something like that.
Q. Yes. Now, as a physician, if a new drug came out for the treatment of a rather benign gynecological condition and the drug under adverse events indicated ovarian cancer, wouldn't you want to know the incidence of ovarian cancer that they saw in their clinical trials with that drug?
MR. WALKER: Object to the form.
A. Sure. I understand what you're saying, yes, sir.
BY MR. RESTAINO:

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Q. Because as a physician, it could be one in a billion.
A. Right.
Q. Or it could be one in one hundred.
A. Right.
Q. Now, when we went through all of the various complications associated with mesh, including erosion, infection, dysuria, dyspareunia, the incident rate of all of them is absent in the IFU, is it not?
A. I'd have to look. But if it's not there, it's not there.
Q. Isn't that important to you as a physician, knowing what's the incidence of an adverse event that the manufacturer knows of before I use this on my patient?
A. We knew those -- I think we knew that information. It just wasn't necessarily in the IFU. It could have been told to us. I know in the presentations that I gave, percentages were in there. Because I know -- I know we didn't have a 16 percent exposure rate when we gave our talks. And we had data to support that. And I have it -- it must be --
THE WITNESS: Jordan, what it could be --
MR. WALKER: Are you talking about this?

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(Indicating.)
THE WITNESS: Yeah. The monograph.
A. And I've not looked at it again, the slide deck. The PowerPoint that we gave, it would have that information. But it was an Ethicon-produced thing. We weren't -- I wasn't going and looking for other data to support it or not to support it.
BY MR. RESTAINO:
Q. Do you know where Ethicon was getting that data from -- let me strike that and give you a little bit of -- inasmuch as Gynemesh PS received 510(k) approval from the FDA based upon ProteGen, therefore it didn't have to go through phase 1, phase 2, phase 3 studies, it was just marketed, where did Ethicon get the data from?
A. I can't speak for Ethicon about the data. I can research that. And I felt like -- I mean in my experience, that the data -- there was nothing that would make me concerned about the adverse effects.
Q. And at the same time you were relying upon Ethicon to present to you accurate and true data; correct?
MR. WALKER: Object to the form.
A. I used Ethicon but I also used my research,

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things that came out in my journals as well.
BY MR. RESTAINO:
Q. Okay. I'm sorry. Now you added things that came out in my journals. But early on there wasn't anything published on Gynemesh PS safety and efficacy; correct?
A. I don't know. I'd have to see. I know that -- you know, there may be some good references in this that we have over there. I need to look at it before I answer that. (Indicating.)
MR. WALKER: Yeah. You're welcome to look at it.
THE WITNESS: It's not this one. (Reading.)
MR. WALKER: And counsel, I just want to clarify. The reason I interrupted you -- and I really try to avoid doing this -- because I was generally confused. I'm understanding your question to be that there were no studies in the literature discussing Gynemesh PS. And I --
MR. RESTAINO: Prior to market approval.
MR. WALKER: Of Prolift?
MR. RESTAINO: Of Gynemesh PS.
MR. WALKER: Prior to 2002?
MR. RESTAINO: So if it went through the

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510(k) approval, there's no clinical trials for Ethicon to publish.
MR. WALKER: Okay. I was understanding you to be working from the premise there was no literature on Gynemesh PS by the time Prolift came on the market. That was my point of confusion.
MR. RESTAINO: Okay. If my question was improperly worded, let the record denote that it was based upon when Gynemesh came out, where is the safety coming from.
MR. WALKER: That's helpful.
MR. RESTAINO: Just so we have as accurate a record as possible.
A. Here's clinical data on exposures and here are these different studies. This is Prolift that we were given as a prof ed and we gave to other doctors that we trained. And it talks about a total exposure rate of 6.2 percent and 2.6 percent here, 549 people. That's only six-month data. But there's 12-month data here that says 10 and 5.6.
Q. And does that tell you where that data is coming from?
A. These are the authors of these studies. (Indicating.) And these are not all Gynecare people.

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Q. Okay. And does it give you the duration of the studies?
A. Yeah. Well, it had follow-up. These were the follow-ups. This is the early data that came out on Prolift.
Q. Okay. All right. So let's look at Jacquetin, if that's how it's pronounced. And again, we mentioned the 16 percent.
A. Right.
Q. And that's higher than you've seen prior?
A. Yeah, correct.
Q. We've already discussed that. All right. We've already asked these questions. We can move on. We're moving along.
(A DISCUSSION WAS HELD OFF THE RECORD.)
BY MR. RESTAINO:
Q. Now, on page 27 of your report you start talking about the Prolift+M?
A. Let me get to that.
MR. WALKER: I was wondering if we were ever going to get there.
MR. RESTAINO: I'm kind of meandering.
THE WITNESS: There's a method.
MR. RESTAINO: Not really. You give me too much credit.
Do you have to take a call or anything?
THE WITNESS: No. Sorry.

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BY MR. RESTAINO:
Q. Now, the Prolift+M kit, the Prolift kit, the Procima kit and the TVT-Secur kit were all removed from the market by Ethicon; correct?
A. Correct.
Q. And Prolift M was removed from the market in 2012; is that correct?
A. Right.
Q. Has anyone representing Ethicon or from Ethicon showed you correspondences between Johnson & Johnson or Ethicon and the FDA about the removal of Prolift+M?
A. No, not officially. Just spoken word. They just told me about it.
Q. Do you have an understanding as to why Prolift M was removed from the market?
A. Well, I think they were all removed when the FDA came up and wanted Ethicon to reinvent the wheel with the mesh essentially and go back to -- they had all this data and they weren't letting them use that data. So they had to start over with their studies.

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So that's -- it's not that they weren't willing to study it. They just thought it was cost prohibitive to go back and do it.
Q. Do you have an understanding of the incidence rate of reporting of adverse events to the MAUDE system regarding Prolift+M?
A. You mean percentages?
Q. Yes.
A. I know about the MAUDE system, but I'm not aware of the percentages at all.
Q. I think earlier you pointed out that the Prolift+M was based upon modifications to Ultrapro?
A. Yes.
Q. Ultrapro mesh?
A. Yeah. Ultrapro mesh and plus M are the same?
MR. WALKER: It's in your report.
A. Yeah, it's here. I think I used that interchangeably. In fact, Gynecare's Ultrapro mesh.
BY MR. RESTAINO:
Q. In your General Reliance List, one of the things you listed was the March 13, 2012 deposition testimony of David Robinson of Ethicon. Does that sound familiar?

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A. Uh-huh (positive response).
Q. Have you read his deposition? Is that one of them that you recall reading?
A. I don't remember reading David's all the way. But I know David well. I say well. I know David.
Q. In there do you recall him testifying that the Prolift+M was developed as a design improvement over Prolift?
A. I don't remember exactly those words.
Q. Do you recall him testifying that the Prolift+M was developed in particular, quote:
"To minimize the mesh load given to the patient and increase the flexibility of the mesh that was being used in the pelvis"?
A. I understand it's definitely a decrease in the mesh load, but I'm not sure as far as it helps with the flexibility necessarily. It was definitely -- I know you don't want me to pontificate. But it was definitely easier to use. It was easy to use as an instrument. You could use it. In your hands it felt a little different. Prolift was great,

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though. They didn't have to improve it as far as I was concerned. But I did use the +M.
Q. Do you recall Dr. Robinson stating the expectation of the change in Prolift+M would benefit the patient both from a safety and effectiveness perspective?
A. I don't remember that.
Q. "Prolift is constructed of knitted filaments of equal amounts of absorbable monofilament fiber and nonabsorbable polypropylene monofilament fiber identical to the composition of Ultrapro."
Correct?
A. Yes.
Q. The Prolift was developed to, quote:
"Overcome the weaknesses of the suture-fixed transvaginal grafts."
Correct?
A. Correct.
Q. And Gynemesh PS was one of those?

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A. Right.
Q. But you don't use that anymore?
A. No. Not because the mesh was a problem. But just because we didn't like the way it was fixed. It was better with the tension-free application.
Q. You write on page 17, actually 17, paragraph C of your expert report --
A. C?
Q. Yes. "After Ethicon's launch of Prolift in 2005" -- do you see that?
A. Uh-huh (positive response).
Q. "We have seen multiple studies showing a superior success rate in mesh-augmented repairs compared to native tissue."
In there how are you defining "superior success rate"? Anatomic, subjective or decreased reoperation rates?
A. All of the above.
Q. All of the above?
A. Yes.
Q. Now, there isn't a reference or citation for multiple studies showing a superior success rate, but

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later in your report you start going through a number of different studies.
A. Right, correct.
Q. Are those the studies you're alluding to?
A. Right. In 45, the next paragraph, that's my pyramid.
MR. WALKER: That's what he was looking for.
A. That's what I was looking for at the beginning.
BY MR. RESTAINO:
Q. Okay. Thank you.
A. I knew I had it in here somewhere.
Q. Now, on page 18, paragraph D, is a study by Withagen.
A. Uh-huh (positive response).
Q. And let's take a look at that study.
MR. RESTAINO: If we can mark that.
THE WITNESS: I think I have it.
MR. WALKER: What exhibit number?
MR. RESTAINO: 22.
(EXHIBIT 22 WAS MARKED FOR IDENTIFICATION.)
BY MR. RESTAINO:
Q. If you look under -- I'm sorry. Are you

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there?
MR. WALKER: Are we on the same one?
A. Yes.
BY MR. RESTAINO:
Q. If you look under results on the abstract, they start off by saying:
"97 women underwent conventional repair and 93 mesh repair."
Would you agree that's not a large study?
A. No. But it's medium size.
Q. Okay. On page 243 -- I'm trying to find it exactly for you. I didn't write it down. They discuss the fact that they underwent randomization. Ah, right column, first paragraph at the top it says:
"After obtaining the signature for the informed consent, patients randomly assigned per center by a computer-generated schedule to either conventional vaginal prolapse surgery or tension-free vaginal mesh. Patients and surgeons were

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not blinded."
The purpose -- do you understand that the purpose of randomization in a randomized controlled trial is an attempt to minimize bias?
A. Correct.
Q. In an attempt to have the two groups as equal as possible?
A. Correct.
Q. If you look at 246, table 1 -- and these are the patient characteristics; correct?
A. Yes.
Q. If you look down under the fifth heading, previous surgery. And then if you slide all the way down, there you see sacrocolpopexy. Do you see that?
A. No. I see here previous incontinence surgery. Oh, previous surgery. Sorry. Go ahead. I'm sorry. Say it again.
Q. The sacro --
A. -- colpopexy, yes.
Q. If you look there in the conventional group, there's six that had that prior surgery, but there's 18 in the group that received the vaginal mesh.
A. Correct.
Q. And that's a statistically significant

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finding because of the P value of 0.1; correct?
A. Right.
Q. So that is, would you agree, a potential source of bias?
A. It could possibly change the results, improve the results from one group.
Q. Okay. Let's put that aside for a moment and look at another study that you discuss, and that's on page 19. You talk about Altman.
A. Altman?
Q. Yes. we'll mark that as 23.
(EXHIBIT 23 WAS MARKED FOR IDENTIFICATION.)
BY MR. RESTAINO:
Q. In your expert report when you're talking about Altman, you write that they:
"... reported in 2011 on the results of their multicenter parallel-group, randomized controlled trial comparing the use of Prolift and traditional colporrhaphy for cystocele repair in 389 patients."

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A. Right.
Q. Correct?
A. Yes.
Q. Now, if you go to page 1834 and their table 4 --
A. Got it, table 4.
Q. -- these are surgical characteristics and adverse events for the colporrhaphy and mesh repair groups; correct?
A. Correct.
Q. And looking under the left under surgical characteristics, for example, and sliding down, there's a statistically significant increase of the operation time in the mesh repair versus the colporrhaphy; correct?
A. Correct. 33 to 52.
Q. And there's a statistically significant increase in estimated blood loss?
A. Correct.
Q. And then down below that there's a bladder perforation listed?
A. Uh-huh (positive response).
Q. Which more occurred in the mesh group?
A. Correct.

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Q. And then two in the mesh group had blood loss in excess of 500 millimeters whereas none in the native tissue procedure had that much blood loss; correct?
A. Uh-huh (positive response).
Q. And 11 patients in the mesh group underwent intraoperative cystoscopy as compared to one in the other; correct?
A. Correct.
Q. Sliding further down under adverse events during hospital stay, you see bladder emptying difficulties?
A. Uh-huh (positive response).
Q. And again, I'm sliding down looking for statistically significant findings.
A. Right, right.
Q. I'm not going to point out everything if it's not statistically significant. But 16 in the mesh group as compared to six had bladder emptying difficulties. And then urinary tract infections was greater in the mesh group, but it was not statistically significant.
A. Right.
Q. So when you're reporting on -- when you were

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quoting Altman, you didn't put in your expert report, though, that there were all these statistically significant adverse events associated with Prolift as compared to colporrhaphy; correct?
A. Yeah. I didn't mention those, but these are pretty mild differences. They are statistically significant. But like estimated blood loss, one is an ounce and the other one is three ounces. There's not much difference. There is a difference. It's statistically significant, but it's not a big difference. It's not going to affect the outcome. And bladder perforation, obviously using meshes, it's going to happen more often if you're having to put instruments in versus native tissue. But it was repaired and it's not of significant consequence. Doing a cystoscopy is just to make sure the ureters are open and all those kinds of things. You could easily do a cystoscopy for a native tissue repair, but they just elected not to do it. So I don't see that as a complication for sure. And it sure wouldn't be anything I'd mention. It's more important with recurrence rate, in my opinion.
Q. Okay. Continuing on page 19, the next study you discuss is Halaska; correct?

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A. Yes.
Q. So let's go ahead and mark that as your next.
(EXHIBIT 24 WAS MARKED FOR IDENTIFICATION.)
MR. RESTAINO: Jordan, it's 24.
MR. WALKER: Thank you.
BY MR. RESTAINO:
Q. This is titled A Multicenter, Randomized, Prospective, Controlled Study Comparing Sacrospinous Fixation and Transvaginal Mesh in the Treatment of Post-Hysterectomy Vaginal Vault Prolapse.
A. It's a mouthful.
Q. It's a mouthful.
Published in 2012. Here if you look under results, there's 168 randomized patients, 83 of whom underwent the sacrospinous fixation, 85 mesh repair. Do you consider that a small, medium or large group?
A. Medium.
Q. "Prolapse recurrence after 12 months occurred in 39.4 percent of the SSF group and in 16.9 percent of the mesh group."

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A. Uh-huh (positive response).
Q. Did I read that correctly?
A. Correct.
Q. And that's what I believe you have put in your expert report; correct?
A. Right.
Q. Now, they then state that the mesh exposure rate was 20.8 percent.
A. Right. Which is high.
Q. That's a high rate; right?
A. Yes.
Q. As a matter of fact, their conclusion here in their abstract is:
"Mesh exposure occurrence was balanced against a lower prolapse recurrence rate in the patients undergoing mesh surgery compared to those undergoing SSF."
Correct?
A. Correct.
Q. Now, if we look at table 2 on page 301.e3.
A. Table 2? Got it.
Q. Now, these are the list of complications in

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each group, in both the SSF and total Prolift group, after three and 12 months; correct?
A. Correct.
Q. After three months, 15.6 percent of patients receiving the mesh had a mesh exposure?
A. Right.
Q. And at 12 months, 20.8 percent had a mesh exposure?
A. Right.
Q. Epidemiologically speaking, that is indicative of trending upward; do you agree?
A. I'm not an epidemiologist necessarily. So at three months you had 15.6 and then you had another -- what is that, about 5 percent that you saw at 12 months. I don't think you can make that, say, at 24 months there was 30 percent. I mean we can't tell. We don't know that for sure.
Q. Right. We'd be speculating one way or the other; agreed?
A. Yes.
Q. But it's trending upward?
A. Those two numbers are trending upward.
Q. Okay. And this study had a 9.52 percent dropout rate at the three-month period; correct?

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A. Let's see here. Is that what it says? 9 percent dropout rate? And to be honest with you, I'm not sure if that's considered high or low.
Q. Well, if we turn to page 301.e6 --
A. Do they mention it?
Q. They do. The middle paragraph. They write:
"One limitation of our study concerns the 9.2 percent dropout rate at the three-month follow-up , which can be attributed to the relatively large number of" --
They lived far away.
A. Yeah, I knew I had looked at that. And there was a reason that was pretty easy to explain.
Q. And at the same time it reduces the power of the study?
A. Possibly.
Q. Would you agree?
A. Yes.
Q. Okay. Now, again, because I didn't want to print out all 341 pages of it, this is the 2013 Cochrane meta-analysis with a separate page I'm going

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to get to. So we'll mark it as a different exhibit.
A. Are you looking somewhere where I referenced it?
Q. This is in your General Reliance List.
A. Where I reference it but not in my report. Okay.
(EXHIBIT 25 WAS MARKED FOR IDENTIFICATION.)
MR. RESTAINO: This is page 22 of the 341 pages.
THE WITNESS: Gotcha.
MR. WALKER: This is Exhibit 25?
MR. RESTAINO: Yes.
Q. Now, if you look at the upper right common:
"Native tissue versus combined total, anterior or posterior compartment polypropylene mesh."
Do you see that?
A. Yes.
Q. They write:
"Data from three trials (Halaska 2012; Iglesia 2010; Withagen 2011) compared

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native tissue repairs with a variety of total, anterior or posterior polypropylene kit meshes."
Do you see that?
A. Yes.
Q. Now, we just discussed Halaska; correct?
A. Right.
Q. And we discussed Withagen?
A. Right.
Q. The one that they don't include here is Altman, which we've just discussed. But they put in Iglesia.
A. Iglesia; right.
Q. Now, earlier in your expert report you discuss a Sokol study, S-O-K-O-L.
A. Sokol, uh-huh (positive response).
Q. Do you recall that briefly?
A. Yes.
Q. And the only reason I state that is because elsewhere here in the review, they point out that Sokol is the one-year update of Iglesia.
A. Okay.
Q. So although we didn't include Iglesia --

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A. We've got Sokol.
Q. -- we've got Sokol.
A. Gotcha.
Q. Now, for the record, these studies that we're discussing now compare the native tissue repairs with a variety of total anterior or posterior polypropylene kit meshes, as you did in your expert report; correct?
A. Uh-huh (positive response).
Q. They write after describing it there:
"While no difference in awareness of prolapse was able to be identified between the groups (25 out of 132, 19 percent, versus 18 out of 123, or 15 percent (relative risk of 1.3 ... confidence interval 0.8 to 2.3)" -- and then they mention it's in analysis 6.1.9 -- "in two trials (Iglesia and Withagen) the recurrence rate on examination was higher in the native tissue repair group as

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compared to the transvaginal polypropylene mesh." Their native tissue with the numbers -- and you can see that for yourself.
"Confidence interval 1.0 to 2."
Did I read that correctly?
A. Yes.
Q. Now, two of the studies with the extension of Sokol are the studies you're relying upon for the efficacy and lack of prolapse; correct?
A. Correct.
Q. Now, Maher here has done a meta-analysis of those randomized controlled trials.
A. Right.
Q. Putting that together, he found no statistical difference, did he?
A. In the awareness.
Q. Correct.
A. But not in the fact that he had a defect. So you had a failure, but you didn't have the awareness of it.
Q. Correct. In the awareness aspect of it. As

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you can see, the confidence interval we mentioned there includes 1.0. Okay. And then if you continue down, the recurrence rate on examination was higher in the native group, as we mentioned, than the mesh group.
A. Where are we? On this same paragraph?
Q. Yes. And then putting the data together, they state:
"The mesh erosion rate was ... 18 percent and ... 9 percent underwent surgical correction for mesh erosion."
A. Uh-huh (positive response).
Q. So the 18 percent is significantly higher when you put all the data for these three RCTs together, isn't it?
MR. WALKER: Object to the form.
A. Yes. That's a bigger number than we normally see.
BY MR. RESTAINO:
Q. "The reoperation rate after native tissue repair was higher after the combined polypropylene mesh kits ...

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compared with native tissue procedures ...."
A. I don't understand that, the way they wrote that. The reoperation rate after native tissue repair was higher?
Q. Was higher. But that's consistent with what you were saying in your expert report.
A. I understand that. The wording is off for me.
"The reoperation rate after native tissue repair was higher after the combined polypropylene mesh kits compared with native tissue procedure ...."
The wording is just off.
Q. Yes, I see --
A. It looks like you were reoperating for the native tissue, but you're reoperating for the mesh exposure; is that correct?
Q. No. My reading about it is consistent with what your expert report said, in that the operation rate after native tissue repair --
A. But that was for failure.

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Q. -- was higher. For failure.
A. For failure. That's what I'm saying. I was thinking for mesh exposure.
Q. So in your expert report --
A. The reoperation rate for failure; right.
Q. -- for two of them. And then Iglesia is the continuation of Sokol.
A. Right.
Q. The reoperation rate, as you point out, is higher in the native tissue --
A. Right.
Q. -- than in the mesh.
A. Correct.
Q. However, here when Maher puts it all together in this meta-analysis, he then points out while it's higher, look at the confidence interval, 1.00 to 1.2. Because it includes unity at 1.0, it's not statistically significant.
So there's three studies that you're relying upon to support your opinion that the reoperation rate is higher in native tissue procedures. But when Maher put all that data together, there wasn't any statistically significant difference; would you agree?
A. Yes. But I mean -- that's what this data

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says, yes.
Q. But this is, as we discussed earlier, this is the gold standard meta-analysis.
A. And the reoperation rate is high. And like I said, this is one meta-analysis in 2013.
Q. Yes.
A. And I don't think we see this in 2016.
Q. We'll get there. We're moving that way. Okay. Now, on page 20, paragraph G, is the Sokol study.
A. Yes.
Q. Now, this is a single study, not a meta-analysis; correct?
A. It's an RCT comparing mesh-augmented colpopexy with traditional colpopexy; right. Results, mesh exposure rate.
Q. Okay. Now, you see the results:
"All 65 evaluable participants were followed for 12 months after trial stoppage for mesh exposures."
So 65 participants is not a large study; would you agree?
A. Correct.

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Q. And the study was actually stopped because a predetermined rate in excess of 15 percent exposure rate was reached.
A. But you also had to see a 15 percent apical Gore-Tex suture exposure rate as well in the native tissue.
Q. Okay. But they didn't stop the trial for that; correct?
A. No. But they were both 15 percent. One was a little higher.
Q. Yes. So if you look at Table 2, page 86.e5 --
A. This is in what? Sokol?
Q. Sokol.
A. Let me get back to Sokol. I've got to find Sokol.
Q. Here it is. I'm sorry. I thought I marked it already. Let's go ahead and mark that next.
(EXHIBIT 26 WAS MARKED FOR IDENTIFICATION.)
A. So where are we now?
BY MR. RESTAINO:
Q. Let's look at table 2 on 86.e5.
A. Okay.

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Q. About the fifth main line down it states Reoperation for Prolapse: Mesh 32, No Mesh 33.
Do you see that?
A. No. Let's see here. Vaginal caliber or complications? I'm looking at this. Oh, you're looking at the table. Okay.
Q. At the table. I'm sorry.
A. Gotcha. Go ahead.
Q. Table 2.
A. Recurrent prolapse?
Q. Reoperation for prolapse. There were three in the mesh group, zero in the no mesh group; correct?
A. Right.
Q. And then further down under Patient Global Impression of Improvement, you see there under mesh and no mesh the numbers also?
A. Uh-huh (positive response).
Q. And then all the way down, Patient Global Impression of Severity, Mesh 26, No Mesh -- if you look at each three of those, none of those are statistically significant findings.
A. Right. I'm looking at -- according to this table; right?
Q. Yes.

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A. But the reason I brought Sokol up was -- (reading.) You're right, it was not statistically significant between the two groups for a lot of reasons. That's the reason I brought it up, more for dyspareunia as well, which was not statistically significant as well.

Q. But what was statistically significant and even more importantly clinically significant is they had to stop this study because of 15.6, I believe, percent mesh erosion rate; correct?

MR. WALKER: Object to the form.

A. Yes, that's why they stopped the study.

BY MR. RESTAINO:

Q. Now, Doctor, would you agree with me that if I was a practicing gynecologist and I had a patient we're considering using native tissue or the Prolift at the time, I'm looking at a randomized controlled trial, albeit smallish, and there's no statistically significant decrease in total reoperation. So the patient is not going to really have an increased risk of reoperation of native tissue. There's no statistically significant difference in patient global impression of improvement between the two, and there's no statistically significant difference in patient

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global impression of severity between the two. But with this Prolift mesh you've got a 15.6 percent risk of erosion that, as we read earlier, could be severe, requiring taking her back to the operating room.

A. That's what this study says. The question is there are other studies that disagree with that.

MR. WALKER: Object to the form to the previous question.

BY MR. RESTAINO:

Q. Now, if we turn to page 86.e6, first paragraph in the middle column:

"Of the 33 no-mesh participants, five ..." -- 15 percent, as you pointed out -- "had apical Gore-Tex suture exposures; two women complained of vaginal discharge and required suture removal in the office at six and nine months after the procedure. One asymptomatic suture Gore-Tex exposure was noted at six months and another was noted at 12

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months; neither exposures required intervention. Another participant had a mild pink discharge and was found to have suture exposure at 16.5 months; however, she was not bothered and chose not to have the suture removed."

So I am accepting, as you pointed out, that there is a 15 percent incidence of the Gore-Tex suture problem, but only two of those patients needed medical intervention.

A. Right.

Q. So just using 15 percent for Gore-Tex suture erosion does not really adequately present the extent of the problem for sutures; would you agree?

A. Possibly. But also the reoperation rate for the mesh exposure was only three, three reoperations for exposure of the mesh.

Q. And I don't mean to get into word games with you, but "reoperation" means bringing back to the operating room under general anesthesia?

A. No question. Correct. And I'm not saying

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that that's not an issue.

Q. And I understand what you're saying. Now, let's look at page 86.e6. And under the Comment section, third paragraph, they write: "The major weakness of this trial" -- do you see that?

A. Yes.

Q. -- "was a lack of statistical power for efficacy outcomes because of premature stopping as a result of reaching predetermined mesh exposure rates of greater than 15 percent. Additionally, some of the complication outcomes may have been inevitable because complications resulted in termination of the study."

Did I read that correctly?

A. Yes.

Q. Now, Doctor, this paper is referenced and written about in your expert report, but your expert report doesn't state this study was stopped because the adverse event limit had been reached, does it?

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A. Right; it does not.
Q. And the authors themselves say this is a major limitation to their study?
MR. WALKER: Object to the form.
A. Yes, that is. The reason this was placed in my report was more talking about the dyspareunia rates versus the mesh exposure or the reoperation rate. You're right, I did not mention the fact that it was stopped.
BY MR. RESTAINO:
Q. Okay. Now, on page 21 you talk about a study that I'm not even going to try to pronounce, B-E-N-B-O-U-Z-I-D.
A. Uh-huh (positive response). It's a four-year follow-up, four-and a half-year follow-up of complications.
Q. This is a retrospective study; correct?
A. Yes. Let me see.
Q. I think I'm just taking this from --
A. Yeah, I think I have this.
Q. -- from your expert report.
A. I have this, yes.
Q. Retrospective study with a total of 75 patients?

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A. Right.
Q. And there's no control group?
A. Correct.
Q. So therefore it's a retrospective case series?
A. Uh-huh (positive response).
Q. And one of the coauthors is Francois Haab, H-A-A-B, who was a consultant for Gynecare; correct?
A. Maybe. I have to see it. Does it say that somewhere? If it says it somewhere, then he was.
Q. Under the conflict of interest disclosure, it's mentioned. But it's a minor point.
Now if you look at your expert report at 21. At page 21 you then cite Landsheere, L-A-N-D-S-H-E-E-R-E. Surgical Intervention After Transvaginal Prolift Mesh Repair: Retrospective Single Center Study Including 524 Patients with Three Years Median Follow-Up."
Did I read that correctly?
A. Yes.
Q. Again, retrospective case series; correct?
A. Let me see. (Reading.) Let me see. 51. I'm sure that's what it is, but let's see here.
"Retrospective study of all

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patients who underwent Prolift mesh repair between 2005 and 2009. 600 consecutive patients."
Okay. Yes.
Q. There's no comparative group?
A. Correct.
Q. There's no control group?
A. Correct.
Q. And there's no randomization?
A. Correct.
Q. Three of the -- excuse me -- several of the authors are consultants for Ethicon.
A. Okay.
Q. If you look under the results of the abstract:
"A total of 600 consecutive patients were identified. 524 patients (87.3 percent) were included in the study with a median follow-up duration of 38 months, range 15 to 63. Global reoperation rate was 11.6 percent."

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Did I read that correctly?
A. Uh-huh (positive response).
Q. And under the conclusion:
"The global reoperation rate after transvaginal Prolift mesh repair was 11.6 percent with urinary incontinence surgery being the most common indication."
Okay. Did I read that correctly?
A. Yes.
Q. So this is the mean -- the mean follow-up for this study was 38 months and the range was 15 to 63.
A. Right.
Q. Now, "mean" is another word for average; correct?
A. Half more and half less, the mean.
Q. That's medium.
A. That's medium.
Q. Mean is the average.
A. Mean is the average. Sorry.
Q. As a matter of fact, once again, that was going to be my next question. Medium is --

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A. Half and half. I'm sorry. Medium, yes.
Q. Now, before we go on --
A. But the reoperation rate in this study was for incontinence, not for recurrent prolapse.
Q. Okay. I want to pull back up the Benbouzid study.
A. Benbouzid. I have it. Benbouzid.
Q. Benbouzid. Previous exhibit, Benbouzid. I'm not sure what I did with my copy.
A. I have it here.
Q. Anyway, hopefully I wrote this properly. Page 4, left column under discussion --
A. Okay.
Q. -- last sentence of the first paragraph.
A. "As a comparison, the long-term studies"?
Q. No. I was reading: "Our initiative is further legitimized."
A. I don't see that, but I may be on the wrong page.
Q. Well, my gut is telling me that for some reason that that's not from Benbouzid but from Landsheere and I just might be getting confused. Why don't we take a moment, take a break.
A. Landsheere is 51.

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MR. WALKER: Let's do that, go off the record.
MR. RESTAINO: Thank you.
(A RECESS WAS TAKEN FROM 2:11 P.M. TO 2:15 P.M.)
BY MR. RESTAINO:
Q. Let's go back on the record and let's look at Benbouzid. And if you go to the discussion, which I believe is on page 4 --
A. Yes.
Q. -- and six lines down, they write: "Our initiative" --
A. There it is.
Q. Got that?
A. Yeah.
Q. -- "is further legitimized by previous expert opinions, underlining that two years should be considered as the minimal postoperative follow-up for evaluating the outcome of pelvic floor reconstructive surgery."
Did I read that correctly?

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A. Yes, you did.
Q. Now, they have a reference there, number 22.
A. Barber.
Q. And 22 is Barber?
A. And Brubaker and Nyegaard, yes.
Q. Okay. Now, at the Landsheere article that we're looking at -- do you have that available?
A. Yes.
Q. On page 83.e5 --
A. Yes.
Q. -- they write:
"In our study the median time of surgical intervention for prolapse recurrence" --
Do you see that?
A. No.
Q. Okay. I'll find it for you.
A. "The rate of surgical intervention for prolapse is 3 percent"? I see that.
Q. Page 83.e5, last sentence, right column down at the bottom.
A. "In our study, the median time" --
Q. -- "of surgical intervention for prolapse recurrence was

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23 months, which may suggest the rate of recurrence increases with longer follow-ups."
Did I read that correctly?
A. Yes, you did.
Q. So as we were discussing -- and it's the median time here that she's talking about now. The median time is 23 months, which means one-half of the patients in this study is less than 23 months. And as Benbouzid, relying on the expert opinion of Barber, points out, 24 months is the minimum for making a clinically important decision; correct?
A. Right.
Q. And then furthermore --
A. Where are we? Furthermore where?
Q. On Landsheere.
A. Okay.
Q. 83.e.2 --
A. Okay.
Q. In the upper right-hand column they wrote that: "76 patients" -- so the right column, third line:
"76 patients (12.7 percent)

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excluded from the study
included 68 patients who were
lost to follow-up and eight
patients who died."
Correct?
A. Right.
Q. Now, 12.7 percent were excluded. As we sit here today, we have no idea what the --
A. Exclusion criteria was.
Q. Or what the failure rate in these patients was; right?
A. Uh-huh (positive response).
Q. So half the patients in this study came in less than 23 months follow-up, and 12.7 percent were lost to follow-up. And so we don't know if 12.7 percent -- if all of them experienced a failure of the procedure and went elsewhere for care, do we?
MR. WALKER: Object to the form.
A. No, we do not. The question is, though, if they had a failure before 23 months, they had a failure before 23 months. The idea is you can't -- those ones that they said failed before 23 months were included. My point is are you trying to say that you can't evaluate failure until after 24 months? Or are

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you just saying --
BY MR. RESTAINO:
Q. Not me.
A. I know.
Q. Benbouzid and Barber were saying that you need a minimum of 24 months in order to make a determination.
A. All right. So you think that -- okay. I gotcha. That's what it says.
Q. Okay. So the only point they're making about the loss of follow-up is if those patients, 12.7 percent, were followed for the full 24 months, we don't know how many of those would have had a failure either, do we?
MR. WALKER: Object to the form.
A. No, we don't know.
BY MR. RESTAINO:
Q. And that's a form of bias in the study and a weakness in the study?
A. Possibly. There are some situations, however, when the patient looks like a failure before 23 months that may resolve.
Q. Which is why they're picking 24 months.
A. That's right. So it could resolve. So that

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number may be smaller as well.
Q. We don't know.
A. Yeah. We don't know that.
Q. We don't know. Okay. Page 22, paragraph J, you then talk about --
A. Hang on. 22 is back to me?
Q. Yes. I'm sorry. Your expert report.
A. Yep.
Q. This is a randomized controlled trial?
A. Uh-huh (positive response).
Q. Comparing colpopexy prolapse repair with and without mesh; correct?
A. With and without mesh; right.
Q. 33 patients had mesh repair, 32 patients had a traditional repair.
A. Uh-huh (positive response).
Q. But as with the Sokol study, this study was also stopped early because of a 15.6 mesh exposure rate, and they saw no statistically significant difference in cure rates between the two groups.
A. Right. That's what it says. And I have that. That's what I say.
Q. Okay. Then 23 K is the real impressive name. You're going to like this one. Dos, D-O-S, and

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then capital R-E-I-S, then capital B-R-A-N-D-A-O, then da, D-A, and last name is S-I-L-V-E-I-R-A -- actually I think that whole thing is the last name because then there's the letter S -- Multicenter, Randomized Trial Comparing Native Vaginal Tissue Repair and Synthetic Mesh Repair for Genital Prolapse Surgical Treatment, published in 2015.
If you look at the abstract, the multicenter, randomized trial included 184 patients with POP-Q stage three or four.
Let me get this article for you.
A. I've got it.
Q. You've got it. Okay. Well, let's go ahead and mark it.
MR. WALKER: You're not going to pronounce the last name on the record?
MR. RESTAINO: I think that was just a challenge. Simone dos Reis Brandao da Silveira.
THE WITNESS: I bet that guy wouldn't stand up.
MR. RESTAINO: Let's mark that.
(EXHIBIT 27 WAS MARKED FOR IDENTIFICATION.)
BY MR. RESTAINO:

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Q. Do you have it, Doctor?
A. Yes.
Q. Again, if you look at the methods under abstract:
"This multicenter, randomized trial included 184 women with POP-Q stage 3 or 4."
Is that correct?
A. Right.
Q. "They were randomly assigned to undergo surgical treatment using native tissue repair (n equals 90) or synthetic mesh repair (N equals 94)."
And further down you can see all those that underwent mesh repair received Prolift.
A. Correct.
Q. Then on the results on the right side:
"Both groups were homogeneous preoperatively. There were no differences between the groups in operative time, complications

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or pain. At one year follow-up , anatomical cure rates were better in the mesh group in the anterior compartment" -- with a P value.
Did I read that correctly?
A. Correct.
Q. "Conclusion: Both techniques were effective. Anatomical efficacy was superior in the mesh group regarding the anterior compartment; quality of life changes were also greater in the mesh group. Complications were significantly higher in the mesh group."
Did I read that all correctly?
A. Yes.
Q. Now, if you go to 336 and figure 1, there's a consort diagram. Do you see that?
A. Yes.
Q. And I'll represent to you in the color

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version that those buttons are blue.
A. Gotcha.
Q. So if you look at the follow-up button, a total of 15 patients were lost to follow-up; correct?
A. Right.
Q. That's 8.1 percent.
A. Correct.
Q. And this was one year follow-up.
A. Right.
Q. So this whole study is less than the two years that Benbouzid and Barber say are necessary for making a determination as to whether the operation is successful or not.
A. That's right. That's what this status says.
Q. And both techniques were effective?
A. Yes. But we had a better repair. They were both repair but a better repair for mesh, anterior repair.
Q. Anterior repair?
A. Right.
Q. At one year?
A. At one year.
Q. Now, if we go back to your study -- no, I'm sorry. You don't have 340 pages to your study, do

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you?
A. It seems like it.
Q. So this study, page 340 in the right column, second to -- right column, second to last, 340 --
A. Right column?
Q. Right column, second to last, it starts off with "another interesting point" -- do you see that?
A. Yes.
Q. -- "regarding the results consists of the complication and reoperation rates. Despite the mesh group presented a higher rate of complications (treatment of mesh exposure, reoperation, rectum extrusion, vaginal dehiscence, and even recurrence), patients' satisfaction was high. On the other hand, the mesh repair provides a better anatomical position of the anterior vaginal wall, around one centimeter higher than

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the native vaginal tissue repair."

Did I read that correctly?

A. You did.

Q. Now, is the one centimeter difference in anatomic results relevant for patient satisfaction?

A. It can be. It can be. One centimeter -- if the overall length of the vagina is six centimeters, one centimeter is a good number. I'm talking about at rest, not when you're having intercourse. So one out of six is pretty good.

Q. Okay. Looking at this study, if a patient, based upon this study alone, was going to be offered the choice between native tissue and Prolift mesh, then she would get the fact that the native tissue procedure was safer with less complications, less chance of the need for recurrent surgery, less chance of recurrence, and equal chance of patient satisfaction with the sole difference between there may be a one-centimeter anatomical difference. Am I missing something?

MR. WALKER: Object to form.

A. No, you're not missing -- that is what it says. But one centimeter -- one centimeter may make a

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difference, especially in how she feels. But this was -- the results on both of these are still -- the point of this being in there is the fact that the anterior compartment was better supported with the mesh group.

BY MR. RESTAINO:

Q. Okay. Now, on page 23 of your expert report, you then discuss Svabik, S-V-A-B-I-K.

A. Right.

Q. Comparison of Vaginal Mesh Repair with Sacrospinous Vaginal Colpopexy in the Management of Vaginal Vault Prolapse After Hysterectomy in Patients with Levator Ani Avulsion.

Correct?

And you write:

"In 2015 Svabik and colleagues published the results of a single-center, randomized controlled trial comparing Prolift use and sacrospinous ligament fixation to treatment post hysterectomy vaginal vault prolapse. At one year

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follow-up, they observed a 3 percent rate of anatomical failure in the Prolift group and a 65 percent anatomical failure rate in the sacrospinous ligament fixation group."

Did I read that correctly?

A. Yes.

Q. Again, one-year follow-up?

A. One year.

Q. So less than two years Benbouzid and Barber write should be considered as the minimal postoperative follow-up for evaluating the outcome of pelvic floor reconstructive surgery; correct?

A. That's what their opinion is, yes.

Q. Benbouzid in the paper that we've marked as an exhibit that you have actually references Barber -- I think it's her reference 22 -- by saying the "published expert opinion of Barber."

A. Of Barber, yes.

Q. Do you recall that?

A. Right.

Q. Now, if you'll look at the abstract of the

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study and the results:

"During the study period, 142 patients who were post-hysterectomy underwent surgery for prolapse in our unit; 72 of these were diagnosed with an avulsion injury and were offered participation in the study. 70 patients were randomized into two groups: 36 in the Prolift group and 34 in the SSF group."

SSF stands for sacrospinous fixation?

A. Yes. Where are we now? I'm sorry.

Q. Oh, I'm sorry. I thought you were following me.

MR. WALKER: Did you mark this?

MR. RESTAINO: This is Svabik. Go ahead and mark this. I apologize, gentlemen. I thought we had done this already and you were following me.

MR. WALKER: No.

THE WITNESS: So we're doing the results?

MR. RESTAINO: Right. I'm sorry.

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THE WITNESS:
"During the study period, 142 patients who were post-hysterectomy underwent surgery for prolapse in our unit."
Is that where we were?
MR. RESTAINO: Slow down. Let's give her a moment to mark the exhibit.
THE WITNESS: I'm sorry.
(EXHIBIT 28 WAS MARKED FOR IDENTIFICATION.)
MR. RESTAINO: She was giving you a look that only a mother gives a child.
Q. Okay. So now my apologies. Now we can go back to the abstract and the results.
"During the study period, 142 patients who were post-hysterectomy underwent surgery for prolapse in our unit; 72 of these were diagnosed with an avulsion injury and were offered participation in the study.

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70 patients were randomized into two groups: 36 in the Prolift and 34 in the SSF group."
Which is the sacrospinous fixation group; correct?
A. Correct.
Q. So in this study 36 patients received mesh. That's not a large study; agreed?
A. Uh-huh (positive response).
Q. Now, on page 367 under results, the second paragraph --
A. 367? I've got it. Results.
Q. The second paragraph:
"At the three-month follow-up, 11 patients in the Prolift group and three in the SSF group were diagnosed with stress urinary incontinence and scheduled for a TVT-O procedure (chi-square P=0.02)."
So that was a statistically significant result; correct?

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A. Uh-huh (positive response).
Q. So when discussing this paper, my point that I wanted to make here is that you don't mention 11 patients in the Prolift group versus only three in the SSF group were diagnosed with SUI and had to undergo another procedure with another thing of mesh. That's pretty significant, isn't it?
MR. WALKER: Object to the form.
A. Well, you know, this was talking about prolapse surgery. And so when you do a prolapse repair, sometimes you have -- after the prolapse is fixed, sometimes it puts undo pressure on the bladder neck. So many times we do incidental, if you will, slings in this situation to prevent this from happening. So they didn't do that. They just addressed the anterior compartment; didn't address the bladder neck. After so long the patient started having incontinence because before they were kinking the urethra when they bared down; because the prolapsed fixed it, they started to get symptomatic. It just means the repair was good. So that's why the reoperation.
Q. But there were only three reoperations in the SSF group, which was a statistically significant

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finding.
A. Right. But the reason that is is because they didn't repair it as well. So if the bladder is not up as well, then they won't have the -- they may not have the incontinence that's obvious to them. I know that sounds -- I'm not trying to be confusing here. But what happens is as we lift the prolapse, we get better support so it puts more pressure on the urethra. In the anterior native tissue, you don't get the support that you would get from the Prolift, so the bladder still sits a little bit lower so they don't get the incontinence side of it. They'll still have the symptoms of the prolapse, but they won't have the incontinence that occurs.
Q. Do they have to have the symptoms of the prolapse or will a certain percentage have symptoms of prolapse?
A. I would assume for them to start -- for them not to develop incontinence, that they either had a previous repair or they did not -- the prolapse was returning. We don't know that for sure. That can explain why there's more need for a repair for the stress incontinence.
Q. Again, I'm trying to determine the

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importance of this. If you were submitting your expert report for publication in the peer-reviewed literature and you were quoting this study, don't you believe you would have to include in that that there was a statistically significant difference in the patients undergoing prolapse versus those undergoing SSF and the number who then have to have a TVT-O procedure performed three months later? Do you not think a peer reviewer would require you to add that?

MR. WALKER: Object to the form.

A. The way I would answer that -- I understand the question. It's a good question. I just think that as a pelvic reconstructive surgeon, some would not be surprised by the fact that you have to go back and do a sling. So there's been a lot of data and a lot of things reported about the need -- in fact, they stopped a study at one time because people were not doing prophylactic sling procedures during repairs. And they stopped the study so that -- because they had so many people that had to go back and do a sling.

BY MR. RESTAINO:

Q. Now, because of the nature of the procedures being performed, would you agree that blinding would be impossible; the patients and the surgeons knew what

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procedure was being performed?

A. Yes, that's correct.

Q. And that's a source of potential bias in any RCT?

A. Sure.

Q. And then despite the anatomical success rate, the study also found a nonstatistically significant difference in the post-op pelvic organ prolapse distress inventory score for subjective outcome.

Correct?

A. Tell me where are we?

Q. Yes. This is Svabik. And if you look at the abstract results section on the right right above conclusion -- do you have it?

A. Right above conclusion?

Q. Right above conclusion:

"The post-op POPDI (Pelvic Organ Prolapse Distress Inventory) score for subjective outcome was 15.3 in the Prolift group and 21.7 in the SSF group (P value of 0.16)."

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So there was not even a statistical difference; correct?

A. Right. There's still a difference.

Q. But the difference could have been due to chance?

A. Possibly.

Q. I mean that's the whole purpose of doing statistical significant testing; correct?

A. Right.

MR. RESTAINO: It's 20 minutes to 3. How about if I stop and give you 15, 20 minutes today so we can stop at 3 o'clock for the good doc. Because as bored as you are and as exciting as this is for me, this is work.

MR. WALKER: Just so we're on the same page, this was noticed for Prolift+M and Prosima. You focused mostly on just Gynemesh PS and Prolift literature in going through his report. Today we'll conclude the prolapse-oriented questioning. Tomorrow is TVT-Exact and TVT-O.

MR. RESTAINO: Oh, okay. See, I kind of -- maybe then I misunderstood you. Because I just thought that we were going to talk generalities of mesh, et al., and then go through the different

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studies. That's all I'm planning on doing tomorrow, is just his studies, which won't take very long. And I was going to do -- there's a few on Prosima. But if you want, I'll cover them today.

MR. WALKER: Let me ask you this: I want to make sure we're on the same page about the time commitment, that we're going to cover everything. I know you've got five hours today, four hours tomorrow, and that's going to cover both prolapse and then the slings; correct?

MR. RESTAINO: Yes; correct.

MR. WALKER: Okay. I'm fine if you want to spend some time tomorrow finishing up with some of the Prolift or prolapse-related literature just so long as we're going to be done with both of his reports tomorrow.

MR. RESTAINO: Oh, yeah. Hopefully very quickly.

MR. WALKER: Yeah, that's fine. That's fine.

MR. RESTAINO: Okay. Then I'll just give you some time today to ask your questions.

MR. WALKER: That will be good.

Can we go off the record?

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(A RECESS WAS TAKEN FROM 2:39 P.M. TO 2:42 P.M.)
MR. WALKER: Doctor, to save some time on the record, could you go to the 2016 Cochrane --
THE WITNESS: Yes. Let's see. Is this 2016? (Indicating.)
MR. RESTAINO: Surgery for Women with Apical Vaginal Prolapse?
THE WITNESS: Wait. I've got it here. Transvaginal mesh 2016. Got it. Sorry.
(A DISCUSSION WAS HELD OFF THE RECORD.)
EXAMINATION
BY MR. WALKER:
Q. Dr. Shoemaker, I want to cover just a couple of things pertaining to your background. You were asked previously by counsel about the total number of mesh procedures that you've done. And I think you testified to having done over 2,000?
A. Correct.
Q. Sling and prolapse mesh procedures?
A. Yes.
Q. I just want to break that down a little bit just so we have a record of approximately how many you've done for each of the prolapse meshes. And like

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we talked about earlier, let's just go with your best estimate --
A. Sure.
Q. -- for what you've done. How many Prolift procedures do you estimate you've performed?
A. At least 500 to 600 mesh -- I mean Prolift procedures.
Q. How many Prolift+M procedures?
A. Probably 100.
Q. And Prosima?
A. Prosima would probably be -- guided mesh would probably be 75 to 100 and Prosima would probably be 50, something like that, if those would add up.
Q. And that's just your best estimate sitting here today?
A. Best estimate.
Q. Is it fair to say you have extensive experience implanting mesh in the pelvic floor?
A. Yes.
Q. And that would include different types of meshes; correct?
A. Correct.
Q. And is it fair to say that every time you treat a patient with mesh and then follow up with that

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patient, you're able to assess the compatibility of that mesh in terms of that patient's experience?
A. Yes. How it reacts to that patient.
Q. And in your experience, have you found guided mesh PS, Prolift and Prolift+M and Prosima to be safe and effective medical devices for treating prolapse repair?
A. Very safe and effective.
Q. And that's in terms of your experience. What about your review of the medical literature? What has that informed your opinions in terms of the safety and efficacy of those products?
A. I feel comfortable with the reviews that I have done both while I was placing the mesh and since the follow-up, the 17-year follow-up with TVT, we've had good safe effective mesh. I have no qualms with using the product.
Q. Let me ask you this: There was a good bit of questioning about the overall recurrence rate of prolapse following surgical repair. Do you remember the various studies counsel opposite showed you suggesting that there's actually a relatively low recurrence rate following a native tissue repair?
A. Yes, I remember that question.

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Q. In your report you cite and rely on the Cochrane review; is that correct?
A. Correct.
Q. And that's a systematic review; correct?
A. Meta-analysis, yes.
Q. And do you consider that to be -- strike that.
On the pyramid of evidence that we've talked about, where does that fall?
A. It's at the pinnacle.
Q. Are you aware of any evidence you could rely on that would be more authoritative than a systematic review like the Cochrane analysis?
A. Not anything more.
Q. And the most recent one pertaining to prolapse repair is from 2016; is that correct?
A. Correct.
Q. I'll direct your attention to it. We're on page 2 of the Cochrane analysis.
A. Yes.
Q. And I'll just direct your attention to this small paragraph on page 2. It reads:
"Recurrent prolapse on examination was less likely

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after mesh repair. This suggests that if 38 percent of women have recurrent prolapse after native tissue repair, between 11 and 20 percent will do so after mesh repair."

Did I read that correctly?

A. Yes.

Q. And how does this inform your opinion about the relative rates of recurrence following a native tissue repair versus a mesh repair when treating prolapse?

A. A mesh repair is much more successful.

Q. And there were a couple of various articles that counsel opposite showed you that I don't think were cited in your report. I want to direct your attention to Exhibit 17, for example. Just because I have it handy, I'm going to show you mine.

A. Which one is it?

Q. This is the Feiner article --

A. Uh-huh (positive response).

Q. -- that counsel opposite was asking you questions about. And I just want to direct your

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attention to the very first paragraph. This author acknowledges at the beginning of the paper that:

"High failure rates after conventional surgeries for pelvic organ prolapse have led to the introduction of graft materials to the field of pelvic floor reconstruction, aiming to reinforce the native issues and achieve improved functional and anatomical outcomes."

Did I read that correctly?

A. That's correct.

Q. Doctor, do you agree that Dr. Feiner in his article is acknowledging that there is a high failure rate for conventional prolapse surgery, hence the need to try to augment it with graft material?

A. Yes. And I also know in my experience I found the same thing.

Q. And let me direct your attention to Exhibit 20. This is the monkey study by Dr. Feola that counsel opposite showed you. Do you remember

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that study?

A. Yes.

Q. And this study examined Gynemesh PS and Ultrapro; correct?

A. Correct.

Q. But I'll note for you at the very beginning of the paper in the introduction even these authors write:

"Of these women, an estimated 13 percent will require a repeat operation within five years, and as many as 29 percent will undergo another surgery for prolapse or a related condition at some point during their life."

Did I read that correctly?

A. Correct.

Q. How does this statement inform your opinion regarding the relative risk of recurrent prolapse following prolapse surgery?

A. It confirms my opinion.

Q. Doctor, you were also shown Exhibit 23. And this is the Altman study. And I believe this is a

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study that you cite in your expert report; is that correct?

A. Yes; correct.

Q. And this is a study that is reliable and authoritative in your field of medicine; is that correct?

A. It is my opinion, yes.

Q. And you were asked various questions about this study. But I want to direct your attention to the conclusion. And by the way, this is a randomized, multicenter controlled trial; correct?

A. Correct.

Q. And in terms of evidence-based medicine, where would a study like this fall on the spectrum?

A. It would be like number 3, very high.

Q. Relatively high?

A. Very high.

MR. RESTAINO: This is Feiner? I'm sorry?

MR. WALKER: No. Now we're on Altman.

MR. RESTAINO: Altman?

MR. WALKER: Yeah. I moved on, Exhibit 23.

Q. So the only type of data that would supersede this in terms of its level of authority would be that from a systematic review or a

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meta-analysis; is that correct?
A. Correct.
Q. And these authors concluded -- and I'm just going to read from the conclusion on page 1835:
"In summary, use of a standardized trocar-guided transvaginal mesh kit resulted in a significantly higher rate of treatment success than did traditional colporrhaphy for repair of anterior vaginal wall prolapse."
Did I read that correctly?
A. Yes, you did.
Q. And this is a conclusion in which you relied on when you were forming your opinions; correct?
A. Absolutely.
Q. And these authors in this peer-reviewed, randomized controlled trial, their conclusion is consistent with your opinions; correct?
A. Yes.
Q. You were also shown the 2013 --

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A. Cochrane.
Q. -- Cochrane.
A. Yes. That was 11.
Q. You were shown it twice. And what I want to do is show you the second version of that.
A. Here it is. It's 13.
Q. Exhibit 25 I think it is.
A. No. This is 16. Sorry.
Q. So do you remember counsel opposite asking you about the fact that Cochrane is looking at the Iglesia/Withagen trials?
A. Yes.
Q. In addition to the Halaska trial?
A. Correct. That I've quoted in there.
Q. That you quote in there. And I believe counsel opposite was making the point that according to Cochrane, there's no statistical significance in terms of the relative rates of recurrence between mesh-based prolapse repair and nonmesh prolapse repair. Do you remember those questions?
A. I remember those questions, yes.
Q. But is it fair to say, Doctor, that you cite in your report additional studies that are not included in this analysis that Cochrane was

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performing?
A. Yes.
Q. For example, the -- now it's my turn -- the Reis Brandao da Silveira study? I think he said it better.
A. Yeah.
Q. That study is a study that you relied on and cite in your report but is not a part of this Cochrane analysis?
A. Yes.
Q. And the same would be true of 2015's Svabik study; correct?
A. Correct.
Q. Both of those studies compared the success rates following mesh and nonmesh prolapse repair; correct?
A. Correct.
Q. And their conclusions are consistent with your opinion in this case; correct?
A. Correct.
Q. And these are all authoritative and reliable peer-reviewed, randomized controlled trials; correct?
A. Correct.
Q. Do you remember being asked questions about

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why Prolift+M was developed by Ethicon?
A. Yes.
Q. Very briefly, Doctor, from your review of the medical literature coupled with your experience, did you find there to be an actual significant difference in terms of complication or success rates between Prolift and Prolift+M?
A. I did not find that at all.
Q. Is it fair to say you found both to be safe and effective products?
A. Both were safe and effective.
Q. And you were asked a number of questions about articles that were not cited in your report or were not on your reliance list. Do you remember that?
A. Yes.
Q. Doctor, when you were writing your report, formulating your opinions in this case, was it important to you to consider the spectrum of literature on the topic --
A. Yes.
Q. -- at hand?
A. Yes.
Q. And would you agree that there are going to be outlier studies on both ends of the spectrum?

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MR. RESTAINO: Objection.
A. Yes.
BY MR. WALKER:
Q. In other words, let's take erosion rates for example. You could have a 7 to 10 percent erosion rate or exposure rate reported in a significant block of literature, but you could also have literature that shows a 1 percent rate and literature that shows a 20 percent rate; correct?
A. Yes; correct.
Q. What is the important criteria for you for deciding what literature is going to guide your ultimate opinions?
A. I like the meta-analysis. It's strong. I like the strength of the study. I also like my own experience. And I like what I find clinically when I do the procedure and when I see the patients and see them for follow-up.
Q. When you were formulating your opinions in this case and writing your report, did you consider medical literature that did not support your conclusions?
A. Yes.
Q. And you read and considered literature that

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did; correct?
A. Yes; correct.
Q. So you were asked some questions about whether or not the IFUs for Prolift -- well, strike that.
You were asked some questions in general about Ethicon's IFUs. Do you remember that?
A. Yes.
Q. Those questions pertained to whether or not there was information about frequency or severity in those IFUs?
A. Correct. And percentages.
Q. Doctor, you had extensive experience teaching other doctors Ethicon prolapse procedures; correct?
A. Yes.
Q. Approximately how many professional education events did you teach?
A. Probably 20.
Q. Would that be all over the country?
A. All over the lower -- the south. It may have been more than that. I'm not sure. From 2005 to probably 2008, it was at least once a month.
MR. WALKER: So I'm going to mark as

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Exhibit 29 what's called the Prolift Surgeon's Resource Monograph.
(EXHIBIT 29 WAS MARKED FOR IDENTIFICATION.)
BY MR. WALKER:
Q. Doctor, this is a document that you're familiar with; correct?
A. Yes.
Q. In fact, Exhibit 29 is a bound copy of the monograph that you personally possess; correct?
A. Correct.
Q. And is it something that Ethicon provided to you before you were ever involved in mesh litigation?
A. Yes.
Q. How did you come about obtaining this document?
A. They gave it to me as a preceptor.
Q. And so what's the purpose of this document?
A. It just -- it's to educate the educators.
Q. And what type of information is contained in it?
A. Everything from all the complication possibilities, all the risks, the patients to use it on, and also the IFU.

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Q. So let me back up. The IFU was part of the information Ethicon would provide to doctors, including yourself, at any prof ed event?
A. Absolutely.
Q. And so even before you were involved in the litigation, you were familiar with the IFUs for the prolapse products that you used?
A. Yes.
Q. Would that include the Gynemesh PS IFU?
A. Yes, it would include that.
Q. You seemed uncertain answering that question earlier. Was that because you didn't read that IFU a couple of months ago?
A. Yes.
Q. But you were familiar with it from your experience in the 2000s using Gynemesh PS?
A. Very much. Very much.
Q. With regard to the Surgeon's Resource Monograph, Doctor, is it fair to say that -- well, strike that.
You read this; correct?
A. Correct.
Q. And this is something that you were familiar with --

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A. Yes.
Q. -- before the litigation began?
A. Absolutely.
Q. And this discusses various potential postoperative complications that can occur following the use of Prolift; correct?
A. Exactly, yes.
Q. And this would apply to Prolift+M as well; correct?
A. Exactly.
Q. And a surgeon would understand that; correct?
A. Correct.
Q. And this discusses postoperative risks of hemorrhage, hematoma, fistula, infection, urinary retention, mesh exposure and erosion, dyspareunia and vaginal pain; correct?
A. Correct.
Q. In addition to just discussing these risks, would you agree, Doctor, that Ethicon provided information to doctors like yourself about the frequency and severity of those risks within the monograph?
A. Yes.

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Q. And for example, there was some discussion about the erosion rate earlier. Do you remember that discussion?
A. Yes.
Q. Doctor, I'll just direct your attention to page 8 of the Prolift monograph. The first sentence of the last paragraph it reads:
"This is to be contrasted with the known occurrence of simple vaginal mesh exposure. It occurs in approximately 3 to 17 percent of cases."
Did I read that correctly?
A. You read that correctly.
Q. So Ethicon is telling doctors like yourself that even up to 17 percent of the time in some reports you could have an exposure?
A. Yes.
Q. And then we'll look -- do you remember being asked questions about where Ethicon was getting their information?
A. Yes.
Q. And do you see here on pages 10 and 11 -- we have a chart on page 10 that identifies various

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studies and exposure and success rates?
A. Yes.
Q. And then on page 11, Doctor, do you see we have citations to 29 different studies on pages 11 and 12?
A. Yes.
Q. Do you see that, Doctor?
A. Yes.
Q. This is referring to peer-reviewed medical literature; correct?
A. Correct.
Q. Like the kind that you cited in your report; correct?
A. Correct. I used part of this in my report.
Q. And this is information that you would have been providing to other doctors as well?
A. Absolutely.
Q. And when you were forming your opinions about the safety and efficacy of Prolift, this is information that you would have been reviewing and relying on?
A. Yes.
Q. Doctor, are all of the opinions that are contained in your Gynemesh PS Prolift, Prolift+M and

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Prosima report held to a reasonable degree of medical certainty?
A. Yes.
Q. Are all of the opinions in your report and those that you testified to here today, are they based on your experience, your education and training, and your review of the medical literature?
A. Yes.
MR. WALKER: That's all of the questions I have for now. But I will reserve the right to follow up at the end of tomorrow's deposition with some other lines of questioning.
MR. RESTAINO: A couple of follow-up questions. Now it gets to the point where it's like a tennis match.
EXAMINATION
BY MR. RESTAINO:
Q. You were asked a couple of questions about the Altman study, the randomized controlled trial, and you were asked about it being at the top of the pyramid other than the meta-analysis.
A. Correct.
Q. If you need to take a look at it, can you just confirm that Altman had a one-year follow-up, did

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it not?
A. I believe it's one year.
Q. Are you comfortable enough testifying to that or do you want to see --
A. Let me look at it real quick just to make sure.
Q. Sure.
MR. WALKER: I just had it. Here it is. Here it is.
A. 12 months, sorry, yes. 12 months.
BY MR. RESTAINO:
Q. Same thing as one year?
MR. WALKER: He's agreeing with you.
A. I'm agreeing with you.
BY MR. RESTAINO:
Q. I know. I'm teasing. It's not a one-year follow-up, it's 12 months.
A. Yes, 12 months, one year.
Q. And then you were asked some questions about the Cochrane 2016.
A. Right.
Q. And before we look at that, 2013 is where you and I spent quite a bit of time on Halaska, and Iglesia and Withagen, and opposing counsel asked you,

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well, now, that didn't include Svabik --
A. Right.
Q. -- and dos Reis Brandao da Silveira; correct? Or something like that.
MR. WALKER: The poor court reporter.
BY MR. RESTAINO:
Q. If you would just take a look at both of those for one moment.
A. Yes.
Q. We'll call them Svabik and the other one.
A. Yeah.
Q. What year were they published?
A. Svabik was 2014 and the other was 2015.
Q. So they couldn't have been included in the 2013 Cochrane review; correct?
A. Correct.
Q. Now, on the 2016 review is I think where counsel asked you about it being the top and finding 38 percent of something, and I kind of got lost there where you were. I apologize. I didn't want to interrupt you. But if you would turn to the Maher 2016, and it's what they call page 2 after the table of contents.
A. Yep.

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Q. If you look down the middle of the page, now they discuss vaginal surgery with mesh versus without mesh. Do you see that?
A. Biologic graft versus native tissue repair.
MR. WALKER: Maybe we're on a different page 2.
BY MR. RESTAINO:
Q. This is Maher, Surgery for Women with Apical Vaginal Prolapse review.
A. No. No, no. This Maher is Cochrane 2016.
Q. Yeah. So is this.
A. This is Transvaginal Mesh and Grafts Compared with Native Tissue Repair for Vaginal Prolapse. You gave me another that was Feiner and Maher.
Q. Yeah. This one is Maher, Feiner, Baessler.
A. Yeah, that's it.
MR. WALKER: John, is this the same thing that you're looking at? (Indicating.)
MR. RESTAINO: No. Look at this. (Indicating.) Cochrane Review, Maher, 2016.
MR. WALKER: I mean what he was citing from -- I'll show it to you. This is his page 2. And I was directing him over here. (Indicating.)

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BY MR. RESTAINO:
Q. So apparently in the same year the authors published two Cochrane reviews. For this one there's vaginal surgery with mesh versus without mesh. And they look at six randomized controlled trials.
A. This is all mesh versus -- absorbable mesh versus native tissue and biologic graft versus native tissue.
Q. Well, that's really interesting. The questions when I gave you the exhibit is this one.
A. But I was using this one.
Q. Okay.
MR. WALKER: I didn't appreciate at the time there was a difference.
MR. RESTAINO: No. Neither did I. Because this has -- when it's comparing vaginal surgery with mesh versus without mesh, first is awareness of prolapse.
"There may be little or no difference between the groups for this outcome. Odds ratio of 0.35 to 3.0. The confidence interval was wide, suggesting if 18 percent of

women are aware of prolapse after surgery without mesh, between 6 percent and 59 percent will be aware of prolapse after surgery with mesh."

Is that included in your document at all?

MR. WALKER: Well, I mean it may be in this. It's a very large document that we have here. We would just have to go through it to find that.

MR. RESTAINO: Okay.

MR. WALKER: I mean we can both do our homework on this, and you can certainly follow up tomorrow on this.

MR. RESTAINO: Okay. We can do that. I'll just spend a moment or two on it. Because this is a 2016 Cochrane review, and it's got some other conflicting data, which is what you're saying, which is why I guess I was so confused.

MR. WALKER: Can we go off the record?

(A DISCUSSION WAS HELD OFF THE RECORD.)

MR. RESTAINO: I don't have any further questions.

MR. WALKER: Nor do I. We'll resume

tomorrow.

(THE DEPOSITION OF MARSHALL SHOEMAKER, M.D., WAS ADJOURNED AT APPROXIMATELY 3:13 P.M. ON JULY 21, 2017.)

C E R T I F I C A T E

I do hereby certify that the foregoing proceedings were taken down by me and transcribed using computer-aided transcription and that the foregoing is a true and correct transcript of said proceedings.

I further certify that I am neither of counsel nor of kin to any of the parties, nor am I in anywise interested in the result of said cause.

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CERTIFICATE OF WITNESS

ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION 2:12-M-02327

I, MARSHALL SHOEMAKER, M.D., do hereby certify that on this _____ day of _____ 2017 I have read the foregoing transcript and to the best of my knowledge it constitutes a true and accurate transcript of my testimony taken on oral examination on July 21, 2017.

_____
MARSHALL SHOEMAKER, M.D.

DATE: _____

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WITNESS TO SIGNATURE

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CERTIFICATE OF CHANGE

ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION 2:12-M-02327

I, MARSHALL SHOEMAKER, M.D., the witness, have read the testimony contained herein and hereby request the following changes be made:

PAGE	LINE	CHANGE	TO

Subscribed and sworn to before me this _____ day of _____ 20___.

My Commission Expires:

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MARSHALL SHOEMAKER, M.D.

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CERTIFICATE OF CHANGE

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